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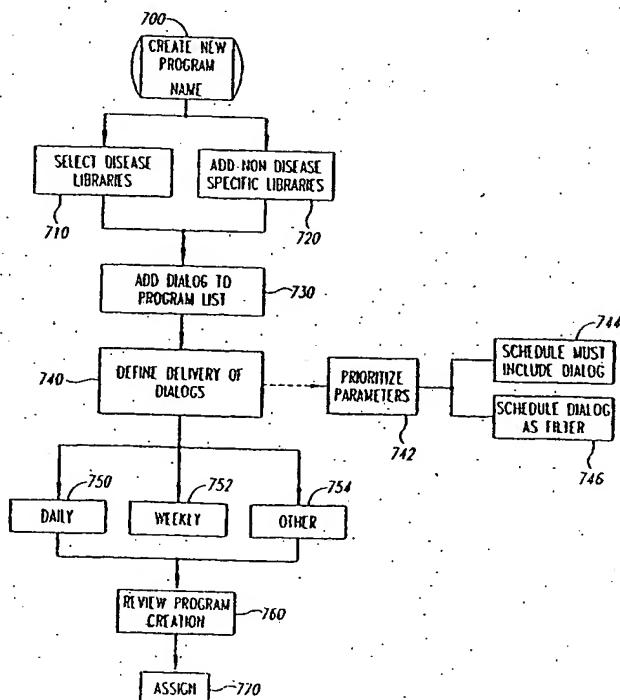
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(54) Title: AN INTERACTIVE PATIENT COMMUNICATION DEVELOPMENT SYSTEM FOR REPORTING ON PATIENT HEALTHCARE MANAGEMENT



(57) Abstract: A modular interactive system and method for customizing health education to an individual at a remote terminal to induce a modification in a health-related behavior of the individual. The first step is to name the future program (700). Next, a user selects the disease libraries (710) from which the program dialogs are created. Simultaneously, the user checks the Utilities Library (720) to add dialogs to the program that are not disease specific like generic greetings. Creating the program is now a simple task of adding dialogs to the program list (730), and to define the delivery of the dialogs (740) as a user can choose specific delivery of the dialogs on a daily (750), weekly (752), or any other (754) programmed timed bases.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

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AN INTERACTIVE PATIENT COMMUNICATION DEVELOPMENT
SYSTEM FOR REPORTING ON PATIENT HEALTHCARE MANAGEMENT

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FIELD OF THE INVENTION

The present invention relates generally to a modular interactive
development system and method for reporting on patient management; and in
particular to an automated content delivery program able to connect remote users
across independent platforms to a central database of libraries whereby a patient's
health can be scored dynamically.

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BACKGROUND OF THE INVENTION

This invention relates to the field of health management, particularly to an
automated interactive system and method for reducing the risk associated with a
monitored client.

For example, the know art includes a number of health-management
systems for providing outpatient services to patients with chronic health
conditions such as asthma and diabetes. However, these systems are incapable of
administering a treatment protocol responsive to the patient's current profile and
of updating the profile in response to the administered protocol.

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SUMMARY OF THE INVENTION

This invention presents a flexible and scalable system in content development for patient management healthcare. Due to the modular object oriented-structure, individual content modules ("dialogs") can be mixed into an unlimited number of updateable customized programs, addressing individual as well as co-existing disease states ("co-morbid") in any combinations, and with automated content variation for improved patient compliance. A dialog is the smallest content object in the FlexCube content structure. Its content addresses issues related to a unique set of symptoms, behaviors or knowledge related to a specific aspect of managing a certain disease referred to as an aspect of care.

In its basic format, each dialog contains questions related to signs and symptoms, behaviors and knowledge with answers categorized as high, medium or low risk answers. For each answer there is a relevant follow up, which can be a teaching statement, an acknowledgment, a motivational statement or a new question that will explore the patient's condition in more depth. While the logical branching within a dialog is driven by patient answers, no dependency exists between individual dialogs.

Dialogs are located in a common pool organized by library. From this library each individual dialog is referenced for participation (appearance) in programs and daily sessions. A dialog's behavior in a program (schedule, position, reporting) is defined at the time of the dialog creation or it is custom defined during the program content selection process. In this way dialogs maintain their integrity while being used and re-used in several client programs. They combine freely with other dialogs in user defined program selections, allowing an unlimited combination of aspects of care and co-existing diseases. Finally, they are easily accessible for revisions and updates.

The present invention provides an object-oriented dialog and modular toolkit structure that enhances quality control options. Also included are the centrally located content objects that offer overview and tracking of the currently

active content, global error correction and global update of content to current standards of care. Because the present invention splits up interfaces for content creation and content selection into separate modules, the present invention exercises control over customer's access to content development in compliance with current and future Federal Drug Administration labeling. Finally the system's structure limits logical branching errors to within a dialog, thereby offering a more robust and less error prone system overall.

Since the content of a dialog and the output of a dialog is related and mapped to a specific aspect of care, the user will have the power and flexibility to model risk evaluation and outcomes reporting around custom selected aspects of care.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing aspects and many of the attendant advantages of this invention will become more readily appreciated as the same becomes better understood by reference to the following detailed description, when taken in conjunction with the accompanying drawings, wherein:

FIGURE 1 is a block diagram depicting a system's compositional and referenced components;

FIGURE 2 is a flow chart diagram depicting the overview of dialog creation;

FIGURE 3 is a block diagram depicting an interdependent characteristics (operators) of a dialog;

FIGURE 4 is flow chart depicting the steps in creating and storing of content data from a dialog;

FIGURE 5 is a flow chart diagram depicting the creation of the programming statements using a Dialog Editor Platform;

FIGURE 6 is a block diagram illustrating the three dimensional aspects of the dynamically determined risk state output scale;

FIGURE 7 is a flowchart depicting the creation of programs using a Program Composer User Interface;

FIGURE 8 is a flow chart depicting a Linker User Interface; and

FIGURE 9 is a flow chart depicting a Reporter User Interface.

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DETAILED DESCRIPTION OF PREFERRED EMBODIMENT

The present invention includes an object-oriented content structure in which the smallest content object, a care specific dialog, is located in a central library from where its characteristics (operators) are composed and referenced by a modular set of tools located at a client computer.

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FIGURE 1 is a block diagram depicting a system 10's compositional and referenced components. Compositionally, the system 10 relies on four system components for dialog or program creation. Additionally, FIGURE 1 illustrates two other system components that interact with the referenced components of the system. A dialog Composer 20, further referenced in FIGURE 2, which is used to author dialog content by an aspect of care. A Program Composer 30, further referenced in FIGURE 7, is a user interfaced click and drag assembly platform for composing programs (a virtual content defined collection of dialogs). On a computer desktop, content dialogs are selected (referenced) for use in disease/client specific programs, with program specific tagging of individual dialog attributes related to frequency (scheduling) and reporting. A Program Patient Linker 40 is a user interface integrated into the desktop on which patients are assigned to programs. During the assignment process patient identification and patient specific metrics are added to the program. A Care Reporter 50, further referenced in FIGURE 9, is a user interface for easy patient result lookup, triage and trend reports. Reporting requirements set in the Program Composer 30 determine which reports are displayed.

Compositional elements of the system 10 reference either one or both of the two remaining components of the system depicted in FIGURE 1. A Program

Scheduler 60, further referenced in FIGURE 8, is an engine for automated scheduling of dialogs based on attributes set in the Program Composer 30, and A Dialog Library 70. The Dialog Library is the principal central location of dialog content units. Dialogs are organized into body system labeled sub-libraries and stored within the Dialog Library 70.

The structure of the system is developed from the integration of the four compositional components as referenced above with the two referenced components and begins with the creation of dialogs in the Dialog Composer 20 as depicted FIGURE 2:

FIGURE 2 is a flow chart diagram depicting the overview of dialog creation and is referenced with more particularity in FIGURE 4. Referring to FIGURE 2, a patient 100 reports on a specific aspect of care 110 (i.e., foot care in a Diabetes Structure) that is addressed by a dialog 125, the smallest content structure of the system, from a disease specific library 120. The basic format of each dialog includes questions 130 related to patient self-management behaviors 132, patient-reportable symptoms 134, or patient knowledge 136. Each question provides a choice for an answer ("output variable") 140 that falls into one of three risk categories; high 142 medium 144 and low risk 146. For each risk category there is an associated follow up 150 which is a teaching statement 152, a motivational statement 154 or a new question 156 that explores the patient's condition in more depth.

While the logical branching within a dialog depends on output variables, no dependency exists between individual dialogs. Dependencies for dialogs exist outside the dialog structure in related operators.

FIGURE 3 is a block diagram depicting the interdependent characteristics (operators) of a dialog 300 in the system matrix. The interdependent characteristics include a Name Label 310 for the aspect of care addressed, a Library 320 that houses a body system specific Localization 325, client specific Programs 330 in which the dialog is being used (referenced), a Schedule frequency

340 by which the dialog is being displayed to a patient in a specific program, definition of Reporting requirements 350, and Patient Identification information 360 and metrics of each individual appliance to which the dialog is assigned.

5 The user interface is easy to use due to the simplicity of program structure in which the user is able to interface with the program and dialog composition aspects of the system. Simply using drag and drop content selection procedures based on a medical decision creates a process familiar to the user. The user decides what aspects of care are relevant for a given program or for an individual patient and in most cases simply selects existing content based on that decision. In 10 all steps of dialog composition, certain steps are taken to make available the dialog in a content library.

FIGURE 4 is a flow chart depicting the steps in creating and storing of content data from a dialog, a user's first task is to name the dialog-to-be-created as depicted in block 400. Next, the user defines the library section of block 410, in 15 which the dialog will reside. The user then identifies an aspect of care at block 420 to which the dialog will primarily refer. Once the naming conventions are assigned and the aspect of care is chosen, the user creates dialog programming statements at block 430, in a graphical programming environment as embodied in FIGURE 5. New dialog content is then stored in an appropriate user library at block 440.

20 The user who has access to create new content does so using a simple dialog composer as embodied in FIGURE 5. FIGURE 5 is a diagram depicting the creation components of a dialog Editor Platform. First, a user is presented with a palette 500 of programming statements that are represented as graphic symbols (icons) that can be dragged from the palette of available statements into a dialog 25 construction platform 505. In a typical embodiment of the present invention, the user drags a start question icon 510 and a three pronged answer icon 520 from an icon palette down to the construction platform 500. The user then activates a dialog box for each icon by clicking on it with a mouse and specifying a question associated with that particular icon, for example, a Start Question Dialog 515.

Next, in an Answer Dialog 524, the user enters three answer options relative to the start question and assigns a raw risk value to each answer 526. The risk values are assigned from high to low with a corresponding text answer. "Yes" equals low risk and "no" equals high risk and "medium" equals somewhere in the middle of low and high risk. Follow up questions icons 530 are dragged onto the construction platform along with an associated answer icon 540. An answer dialog 545 is then prepared. Clicking on the output icon 550, the user activates the output dialog box 555. Here the user defines risk state output 558 in detail, further depicted with more particularity in FIGURE 5, defining the position of the answer relative to the axis of the risk cube. At any time during or after the dialog creation process, the user can review the dialog created, using a simulation interface to an appropriate appliance or in the alternative, the user can review the actual dialog content in a text only overview window. Once all the follow up questions, answers and output dialogs are formulated and put onto the construction platform 525, the newly created dialogs are store in a user library 560 from where it can be referenced for participation in any user defined care management program or for later updating or editing.

FIGURE 6 is a block diagram illustrating the three dimensional aspects of the dynamically determined risk state output scale which in the Dialog Composer, FIGURE 5, is referenced at block 558. The X-axis 610 scales whether the answer to a question dialog sets the risk at a certain risk level on a 9 point risk scale or whether the answer moves the patient risk state in a certain direction and by how much, thereby creating an accumulated risk profile. Additionally, the answer to a dialog is incorporated as a value in a mathematically calculated risk state that may incorporate other answers as well, creating a composite, weighted risk state. The Y-axis 620 refers to the actual aspect of care in which the risk will be incorporated. The Z-axis 630 incorporates the expression of risk 530, i.e, whether the risk is assigned to a sign or symptom 632, a behavior 634, or a knowledge expression 636. This dynamic model allows for very sophisticated risk profiling

including risk trend alerts, composite risk profiling by aspects of care and profiling by risk expression. The dynamic risk "foot prints" available at any time can serve as triggers for automated content selection.

Once dialogs are named, created and assigned to an aspect of care and the risk output is assigned to the appropriate dialog, a user of the system can then use the Program Composer 30 to create the program that eventually is assigned to a patient.

FIGURE 7 is a flowchart depicting the creation of "programs" using the Program Composer User Interface ("UP"). The UI is a platform for selecting library resident Dialogs created as depicted in FIGURE 6, for participation in user-defined care management programs. In a typical embodiment of the present invention, the first step is to name the future program block 700. Next, at block 710, a user selects the disease libraries from which the program dialogs are created. Simultaneously, at block 720, the user checks the Utilities Library to add dialogs to the program that are not disease specific like generic greetings. This gives the user access to the detailed content of both of these libraries organized by aspects of care and their respective dialogs. Creating the program is now a simple task of adding dialogs to the program list, see block 730, and at block 740 to define the delivery of the dialogs as a user can choose specific delivery of the dialogs on a daily 750, weekly 752, or any other 754 programmed-timed basis. Additionally, at block 742, a user checks the priority of dialogs to set parameters necessary for the correct scheduling of the dialogs in the program. Options are to force the scheduler to include the dialog block 744, or to assign dialogs as fillers, block 746. The later could be the case, for example, with trivia type dialogs, entertainment dialogs etc. Also, the user has the opportunity to decide the placement of dialogs in daily sessions. Greetings, for example, should be checked as "always first." The user can review the complete created program using the "View Selection" link, block 760. Using a very simple interface, the user has now created a totally custom made program. At block 770, the program is now

available for assignment to any of the user's patients or for later modification by the user by adding or deleting dialogs. The present invention embodies the assignment by way of a Linker User Interface ("Linker UI") as depicted in FIGURE 8.

5 FIGURE 8 is a flow chart depicting the Linker UI, which is a platform for assigning or "linking" care management programs to patient populations or to individual patients. The first step at block 800 is to retrieve patient's name(s) to be used on the work platform through a filtering or sorting procedure defined by the user. Next, at block 810, the user marks the patient(s) and the care management
10 program to be assigned. Finally the user creates the "Link" to activate a dialog box that allows the user to specify a time frame in which the program will run for the selected patient(s), block 820. Should the user wish to link the patient to other programs all that is needed is to repeat the process. To process the linking of an entire population or part of a population a user selects all patients, block 800, and
15 assigns all of them, block 810, to a program.

 The last step in the creation of a system program is the creation of a Reporter User Interface ("Reporter UI") which creates patient reports specific to patient results that in turn can initiate program actions based on those results. FIGURE 9 is a flow chart depicting the Reporter UI and the creation of reports.
20 The layout of the Reporter UI is completely consistent with that of the Linker UI depicted in FIGURE 8. First a user retrieves patient names through a filtering process, block 902. The user filters, at block 900, names through the programs by either risk search, block 904, the aspects of care, block 905, within each program, or the risk expression, block 906, as defined as a symptom, behavior or
25 knowledge, block 908, factor. This is done to allow a user to trend a risk profile, block 910, for the patient in the aspect of care where the patient has scored, for example, a high-risk profile as depicted in FIGURE 6. A user can configure the Reporter UI to display block 920 the actual answers or results that led to the exemplified high-risk profile. Lastly, at block 930, a patient is assigned to a program

based on the risk profile or Aspect of Care. Reports assigned to patients can now for example, allow the user to see details for each aspect of care, order a report printed or write a note that will be associated with a linked event.

5 While this invention has been described in terms of several preferred embodiments, there are alterations, permutations, and equivalents that fall within the scope of this invention. It is therefore intended that the following appended claims be interpreted as including all such alterations, permutations, and equivalents as fall within the true spirit and scope of the present invention.

CLAIMS

What is claimed is:

- 5 1. A system for coding and updating a patient profile and for providing customized health information to an individual, said system comprising:
- a server;
 - a remote interface for entering in said server questions to be answered by said individual; and
 - 10 a remotely programmable apparatus for interacting with said individual, said remotely programmable apparatus being in communication with said server via a communication network;
- wherein said server comprises:
- a questionnaire generator for generating a questionnaire comprising 15 questions for determining at least one of a physical condition of said individual, a mental condition of said individual, and a behavior of said individual, and for transmitting said questionnaire from said server to said remotely programmable apparatus;
 - a data gatherer connected to said questionnaire generator for receiving 20 from said remotely programmable apparatus said individual's physical condition into a physical condition profile, said individual's mental condition into a mental condition profile, said individual's behavior into a behavioral profile for said individual according to responses to the questionnaire;
 - a script generator connected to said data gatherer for generating a 25 customized script program from questions based on said individual's physical, mental, and behavioral profiles, and for transmitting said customized script program to said remotely programmable apparatus;
 - a report generator for generating a report comprising said individual's physical, mental, and behavioral profiles and said assigned customized script 30 program; and
 - a database connected to said questionnaire generator, said data gatherer, and said script generator for storing said questionnaire, said profiles, and said script program;
- and wherein said remotely programmable apparatus comprises:

a communication means for receiving said questionnaire and said script program from said server and for transmitting said responses to said server;

a user interface for communicating said questionnaire and said script program to said individual and for receiving said responses;

5 a memory for storing said questionnaire, said script program, and said responses; and

a processor connected to said communication means, said user interface and said memory for executing said questionnaire and said script program to communicate said questions to said individual, to receive said responses to said questions, and to transmit said responses to said server.

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2. The system of Claim 1, wherein after said responses are transmitted to said server, additional physical, mental, and behavioral profiles are created and an additional script program is created.

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3. The system of Claim 1, wherein said questionnaire generator further comprises a registration means for registering a name of said individual, a language of said individual, and a current health condition of said individual; and said questionnaire generator and said script generator comprise a tailoring means for tailoring said questionnaire and said script program in dependence upon said language and said current health condition of said individual.

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4. The system of Claim 1, wherein said questionnaire generator further includes a confirmation means for confirming with said individual said physical profile, mental profile, and behavioral profile.

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5. The system of Claim 1, wherein said script program comprises:
a request for clinical data;
a monitoring question; and
educational information.

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6. The system of Claim 5, wherein said educational information comprises means for accessing an external source of additional educational

information and means for transferring said additional educational information from said external source to said remotely programmable apparatus.

7. The system of Claim 1, wherein said data relating to said physical condition of said individual comprise measurements which are received from a monitoring device connected to said remotely programmable apparatus.

8. The system of Claim 1, wherein said data relating to said physical condition of said individual comprises medical claims received from a managed care organization of said individual.

9. The system of Claim 1, wherein said data related to said physical condition of said individual comprises electronic medical records received from a health-care provider of said individual.

10. A method for providing customized health information to an individual to induce a modification in a health-related behavior of said individual, said method comprising:

exchanging data with a server through a communication network, wherein said data includes a questionnaire and a script program executable by said remotely programmable apparatus to communicate questions to said individual, to receive responses to said questions, and to transmit said responses to said server;

storing said questionnaire, said script program, and said responses to said questions;

communicating said questions to said individual and for receiving said responses to said questions; and

executing said questionnaire and said script program;

transferring from said server to said remotely programmable apparatus said questionnaire containing questions for determining a physical condition, a mental condition, and behavior of said individual;

receiving in said server responses to said questions entered by said individual from said remotely programmable apparatus;

generating from said responses a physical condition, a mental condition, and a behavior of said individual;

- translating said physical condition, mental condition, and behavior into physical, mental, and behavioral profiles of said individual;
generating a customized script program for said individual based on said physical, mental, and behavioral profiles; and
5 transferring said customized script program to said remotely programmable apparatus.
11. The method of Claim 10, further comprising creating additional physical, mental, and behavioral profiles and an additional script program after
10 said server receives said responses.
12. The method of Claim 10, further comprising registering a name of said individual, a language of said individual, and said current health condition of said individual in said server prior to transferring said questionnaire; and tailoring
15 said questionnaire and said script program to said individual in dependence upon said language and said current health condition of said individual.
13. The method of Claim 10, wherein said script program comprises:
20 a request for clinical data;
a monitoring question; and
educational information.
14. The method of Claim 13, wherein said educational information comprises means for accessing an external source of additional educational
25 information and means for transferring said additional educational information from said external source to said remotely programmable apparatus.
15. The method of Claim 10, further comprising generating a report comprising said individual's physical, mental, and behavioral profiles and said
30 assigned customized script program.
16. The method of Claim 10, wherein said data relating to said physical condition comprises measurements which are received by said server from a monitoring device connected to said remotely programmable apparatus.

17. The method of Claim 10, wherein said data relating to said physical condition of said individual comprises medical claims received from a managed care organization of said individual.

18. The method of Claim 10, wherein said data relating to said physical condition of said individual comprises electronic medical records received from a health-care provider of said individual.

19. A clinician computer system, the clinician system in communicating with one or more patient device, the clinician system comprising:
a database comprising questions, answer and follow-up actions;
a display;
a processor; and
a graphical user interface executed by the processor and presented on the display comprising:
a selection component for selecting a question, answer or follow-up action from the database;
an icon generator for generating and displaying an icon associated with the selected question, answer or follow-up action;
a linking component for linking displayed icon; and
a conversion component for converting linked displayed icons into a script program;
a sending component for sending the script program to a patient device over a communication network.

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APPENDIX A

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**FlexCube 2000
Prototype Requirements
and Implementation Notes**

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Executive Summary

Introduction

The FlexCube System has the potential to meet HHN's current and future patient management requirements. A prototype system is under development, providing a platform for testing and further investigation of this system. See the section on Strategic Requirements for more detailed information about FlexCube.

Ultimately, a production implementation of this system will be different from this initial prototype. The prototype system will fit on a laptop computer and use a Windows GUI for all functionality. A production system would differ in several respects. The patient management portion would run as a thin-client Web-based application. Minor adjustments to the UI would be required in this conversion. The database used for initial testing will not be scalable to handle full production volume. However, the schema should be relatively easy to migrate to a full production database, such as Oracle.

This prototype is not meant to be the final system implementation. It will allow HHN to develop and explore the FlexCube concept. Many of the new software objects will be reusable in later stages of development and hopefully by the core engineering group. The ultimate goal is for this system to radically improve content development and patient care, while reducing the human resources necessary to manage a given population.

Implementation

The initial prototype will be developed to run on a single laptop computer. A serial cable will connect the laptop to a Health Buddy appliance, enabling round-trip communication. The prototype will only be able to distribute content to remote appliances by tapping into HHN's existing data-center infrastructure. Difficulties are expected in mapping patient response and risk-analysis data between the two systems since they are based on completely different paradigms. However, it should be straightforward to convert FlexCube sessions into traditional surveys to allow patients to test raw output from the system. This conversion will be explored more fully in the near future. Another option is to build a mini-patient server to allow larger scale testing.

Several new "objects" will need to be developed in order to implement the FlexCube system. Cube and dialog objects are at the core of the system. These objects will require a Health Buddy Database (BDB) and enhanced scripting language in the appliance to fully operate. A single schema will be leveraged to act as both remote and data-center database. Ultimately, content will be composed off-line and exchanged as BDBs between the data-center and remote installations.

Desktop Applications will be developed under Windows using Borland C++ Builder 4. This system includes many pre-packaged GUI controls and database support necessary for prototype development. Care will be taken to avoid using non-standard database and GUI techniques, easing migration to a larger system.

Plans will be finalized for the FlexCube prototype architecture, resulting in an Application Server Schema, Windows GUI design, Application Server Requirements, Appliance Application Requirements. The final design should allow application servers to become modules, like a Lego set. For example, each care manager in an organization could have a full application server. A separate DSS server could track content and results for aggregate reporting.

Appliance development will be based on the DemoBox project. Structures and BDBs will be developed and integrated into the scripting language. Later, a library of script sub-routines will utilize these features to support the cube and dialogs required by the FlexCube system.

The NBV DemoBox Composer application will be leveraged into a dialog editor for the FlexCube system.

Resource Utilization

Erik Jensen (Creator of the FlexCube concept) – Will provide overall management, direction in the functional and user-interaction portions of the system.

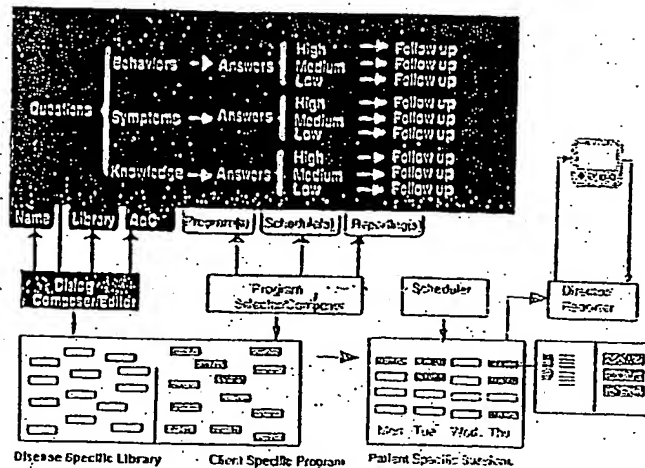
Daniel Lindsey – Will provide engineering direction and guidance throughout the production of the prototype system. Work with Albert Bodenhamer to design databases.

Albert Bodenhamer – Will be responsible for implementing Windows GUI and database portions of the system.

Adam Wozniak – Will be responsible for implementing the enhanced scripting language and support-scripts.

Eric Smith – Will be responsible for implementing BDBs, VM support, appliance file system, and communications.

FlexCube



System Components

- **Health Buddy Database (BDB)** – A micro database object that moves cube content, dialogs, and raw response information to and from the appliance via XML.
- **XML Schema Objects** – For transporting Patient Cubes, Dialogs, Box Control Info, etc.
- **Application Server Schema** – Stores patient data, patient demographics, personalized program/dialog content, patient cube-state, and raw response data

Applications

Appliance

- **Box Manager Application** – High level control over appliance functionality, implements to-do list
- **Session Manager** – Manages To Do list, launches content applications
- **FlexCube Presenter App** – Provides sessions by executing dialogs and updating cube state
- **User Login Manager** – Enables patient login and authentication
- **Communications Manager** – Overall responsibility for non-conversational communications
- **Connection Manager** – Brings up physical connection
- **Login Manager** – Responsible for logging into host system
- **Mail Exchange Manager** – Responsible for data exchange between appliance and host

Windows GUI

- **Administrator Application** – Provides system maintenance and data entry features, account setup, patient entry, etc.
- **Dialog Editor / Composer** – Enables the creation and maintenance of non-personalized dialogs within libraries, dialog labeling, and import/export capability to the application server database
- **Program Selector** – Selects dialogs from libraries in and out of content specific programs, specifies labels for scheduling and reporting
- **Personalizer** – Maintains patient-specific cube metrics, defining risk levels, etc.

- **Session Scheduler** – Semi-automatic creation and scheduling of patient specific sessions
- **Reporter** – Patient results lookup organized into levels from patient-specific program overview to raw results from particular session, including graphical body system view.

Future Additions

- **Enhanced Scripting Language** – Enables the appliance to manipulate BDBs, supporting raw data-collection and cube/dialog interaction
- **Appliance Apps** – Script Language implementation of appliance applications.
- **Thin-Client Reporter** – Allows system access via the Web
- **Global Patient List Server** – This server maintains a list of all patients that HHN has serviced. As new patients are added, they will be assigned a Globally Unique ID, which will follow them around our service.

Implementation Strategy

Milestone 1 – Build Foundation and Design System

Initially, construction will begin on foundation objects and code while design decisions are being finalized for the system architecture. Foundation work includes BDB implementation, Enhanced Script Environment, and enhancements leveraging NBV Composer into Dialog Composer. The final system will require these components regardless of database & GUI design. These components will all be integrated into the final release. System architecture, project schedule, GUI design and other project decisions will be completed in parallel.

- Rough-draft GUI design
- Project Schedule
- Scripting Language Selected
- Architectural decisions finalized
- Rough-draft application server schema
- BDB library code, suitable for integration onto appliance and Windows
- Enhanced Scripting environment with HAL support
- Dialog Editor with branching, calculation nodes, decision nodes, etc.

Milestone 2 – Present a Session on the Appliance

By Milestone 2, the appliance will be capable of downloading a session generated by the Windows apps and present the session to a patient.

- Finalized Schema
- Finalized GUI design
- Windows apps scheduling content into sessions
- Windows apps generating output XML
- Appliance reading content XML into internal format
- Presenter application on appliance able to read BDB and present a session

Milestone 3 – Round-Trip between Server and Appliance

By Milestone 3, the system will be able to generate sessions, run them on the appliance, retrieve the results, and display raw and refined results.

- Windows apps sending scheduled session content and receiving results over the serial cable
- Appliance presenting the session and recording results
- Windows apps uploading results from appliance and displaying raw response and cube data

Milestone 4 – System fully Alpha

By Milestone 4, the appliance will be polished and dependable through the serial link. The Windows apps will be fully functional and include all essential functionality to make the system work. Wizards will have been added to support appropriate system functions, especially for content composition

- Windows apps generating reports and displaying patient status
- Wizard functionality in Composer and key parts of Reporter
- Appliance ready to demo

Strategic Requirements

Database Highly Scalable

We ultimately need to support 10's of thousands of users and Millions of appliances.

Portable Content and Results

Other appliances and systems should be capable of presenting and processing our content

Secure and Reliable

The system must provide controlled access to patient data, system functionality, and maintain secure communications

Automatic Generation of Adaptive Content

The system should focus content where each individual patient requires the most attention. This needs to happen automatically so that we can support very large patient populations with a small group of Care Managers.

Multiple Patients per Appliance

This will open up the possibility of installing appliances at centralized locations, such as pharmacies. This will also enable families to share an appliance within a home.

Multiple Content Senders

Each patient using a Health Buddy needs the ability to subscribe to multiple content providers. For example, a patient from Kaiser might subscribe to a diabetes program, a weightloss program, and a health newsletter from another organization.

Multi-Lingual Parallel Content

The system must support the large number of non-English speakers throughout the US. This feature creates the potential for a global marketplace.

Independent Appliance Decisions based on Patient Data

Immediate Patient Feed-Back

Ability to Score SF36 on Appliance

Ad Hoc patient communication

Care providers need to be able to send personal messages and queries outside of a patient's normal programs.

Appealing Graphical UI

The Graphical User Interface must be pleasant for the care providers who will be using our system for hours at a time.

Interface to Patient List Server

This system needs to communicate with a centralized server that issues Globally Unique Patient Ids. This will facilitate knowing that John Smith at Kaiser is the same John Smith at Stanford's Clinical Research Program, etc.

WO 01/69505

PCT/US01/08614

Reports Summarized by Hierarchy Structure

This will enable the system to mesh with future Information Systems.

System Components

Application Server Schema/Database

The Application Server Schema is the heart of the FlexCube system. All data flows in and out of the database. Content development generally occurs offsite on a fat client installation. Content is imported and exported between the installation and the actual data center. Initially, fat client tools will be used for managing patients and reviewing results. In the next phase, thin client tools will enable Internet access via the Web.

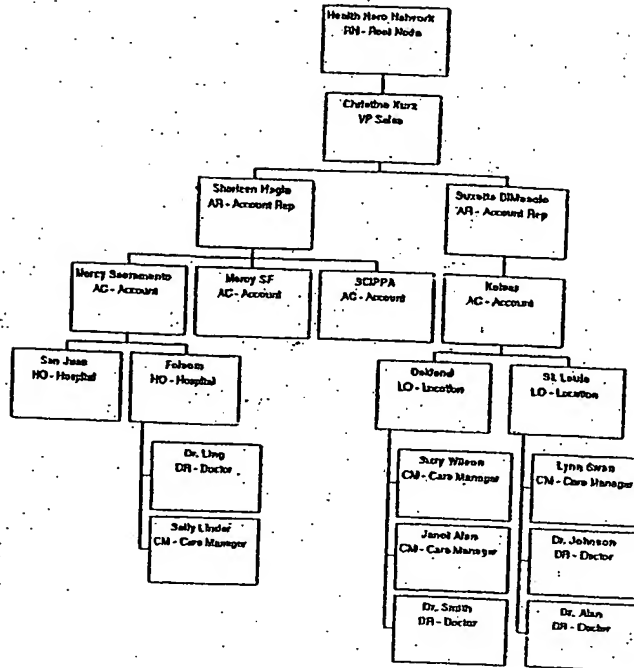
Requirements

- As simple as possible to support scaling – support 10's of thousands of users and millions of appliances
- Fast Cube state retrieval for an arbitrary date/time stamp enabling reports to be generated quickly
- Accounts are always responsible for their own programs
- Ability to Import and Export content between Application Servers
- Ability to aggregate data from multiple Application Servers for generating aggregate DSS reporting
- Support Arbitrary Client Hierarchy
- Support the following Objects
 - Account Entity / Hierarchy – Support arbitrary account hierarchy
 - Group – Allow Care Managers to arbitrarily group their patients
 - Patient Notes
 - Patient
 - Patient Demographics
 - Medications
 - Escalations
 - Patient Cube States
 - Program
 - Dialogs
 - Raw Response Data
 - Program Session Schedules

Components / Schema Objects

- System Table – Include Server GUID
- Account Entity / Hierarchy
- Group
- Patient
 - Demographics
 - Acct Entity Notes
 - Medications
 - Escalations
- Program
- Patient Cube – One Cube per Patient or Multiples for each program?
- Dialog
- Response Data
- Session

Sample Application Server Hierarchy



Account Entity / Hierarchy

Account Entities are like entries on an org chart. The schema supports several different types of entries or nodes. The hierarchy is split into two main sections: HHN and Account. The top portion is reserved for HHN's sales structure and the bottom portion is available for account entries. Much of the structure in both sections will likely be filler. By modeling both HHN's and the account's structure, the system will be able to produce reports summarized by each level up and down the hierarchy.

In order to operate, the system needs several specific types of entries. HHN's Root must be at the top in each Application Server. Logging into the system as root disables all security features and enables system maintenance features. Account Representatives must be at the bottom of HHN's portion. Filler entries allow HHN's real sales structure to be modeled.

Only account entries can be entered under an HHN Account Representative. Programs that are shared within an account will be associated with these account entries. These entries establish the root of each account within the system.

Doctors and Care Managers are always at the bottom of an account's hierarchy. These are considered the users of the system. The system will only allow patients to be assigned to these entries. Filler entries can be created and placed between each Account Entry and the users to model the account's actual structure. Some accounts may want to see reports organized by Division, City, Hospital, Users, and Patients, while others may simply want Location, Users, and Patients. The simplest form is to enter all users directly under an account.

Access rights and privileges within the system will be associated with each entry. The root entry is special since this account has full access to the system. Some entries, such as location, may not even be allowed to

log in, as they only establish a reporting framework. Access to various applications and features within the system will be set on an entry by entry basis. Some Care Managers may be granted more privileges than others.

Programs are tied to these hierarchy entries. Programs that are tied to a user (Doctor or Care Manager) will be considered private. Whereas, programs tied to an account are considered shared. The system will support

Implementation Notes

Scaling

Several tactics have been employed to support ten's of thousands of users and millions of appliances. An account must fit on a single Application Server. However, utilizing SuperNova, an arbitrary number of Application Servers may be established to spread the load.

By configuring the SuperNova distribution of new content and results to send copies to an aggregation server. Aggregation reports, combining data from multiple accounts, can be generated in parallel by combining data from many servers while the individual Application Servers continue to run, supporting users and appliances.

Normally, an account database can not be split across multiple servers. However, the possibility of spreading the load is possible by utilizing replication technology. Oracle is one of many database systems with automatic replication services. This permits multiple Care Managers and Doctors within an organization to each operate on a local database and stay in sync with the centralized organization server. Again, this provides a way to scale servers and ultimately grow the system to very large sizes. This is probably not low hanging fruit. The amount of effort necessary to implement this setup is not known at this time. However, this problem has already been solved in other systems.

The depth of the content hierarchy has been kept as shallow as possible to remove the likelihood of recursive queries. Wherever possible, the schema has been designed so that all related elements can be grabbed in one query and assembled or sorted within the client.

Efficient Hierarchy / Database Interaction

Rather than implement recursive SQL queries to grab and build hierarchies. Use the account index to grab all entities with one query. The HHN hierarchy can also be retrieved using the same method. If necessary both can be retrieved in a single query by combining (acct# eq searchacct#) or (acct# eq 'CORPHN').

Cube State Retrieval

Retrieving a Patient's Cube State for a given point in time will occur very often during system processing. The most efficient means we've found of retrieving a cube uses the following mechanism:

1. Cube Metrics or Values are stored in a table indexed by Cube ID, AoC, Expression, DateEffective.
2. An additional field is added to this table called Replaced Date.
3. A Database trigger is responsible for updating the Replaced Date field whenever a new record is inserted. This places the update in the most efficient place, saving wire-time, SQL parsing, etc.
4. This enables a single query to grab the entire cube for a given patient at a given time as well as the current state by using the following queries:
 - select * from metric where patient_id=our_patient and create_date<search_date and (isnull(replace_date) or replace_date<search_date);

Content Exchange

App Server #'s must be globally unique

Account#'s

Globally Unique Object ID's

Combining Account# + CM ID, etc in BDBs allowing diff Recnums in different schemas

Data Aggregation Patient GUIDs

Using Database Replication to spread load within an organization

Program Security

The security model in FlexCube is tied to Account Entities. Account Entities will be granted or denied access to critical system objects and applications on a per user basis. Only the Root HHN account will be able to access data across accounts. Encryption will be used to protect patient data over the Web.

Status Group

Status groups are a standard mechanism for tracking the status of patients, account entities, programs, and many other objects within the system. Each status group consists of Current Status, Previous Status, Transaction#, Transaction Date, and Date Effective. Each object has a private set of codes, reflecting all the states unique to that object. These are kept in the centralized STATUS_CODES table within the schema. The STATUS_HISTORY table keeps track of all changes made to each object's status.

Features:

- Current Status – Is this an active patient?
- If Current Status is the same as Previous Status, the object status has never changed
- Status History, allowing the system to know what an object's status was at any given point in the past
- Efficient synchronization of objects between Application Servers

Whenever a status change event occurs, the following database changes are triggered:

- The Current Status is copied into the Previous Status
- The Current Status is changed to the new status code
- The Transaction date is updated
- A new System Transaction # is assigned and filled in
- The System Date/Time is put into the Date Effective field
- The Database record is updated in the database
- A new STATUS_HISTORY record is created with the following info: Status, Previous Status, System Transaction #, Transaction Date, and Date Effective

Thoughts

- Can we roll question node children into a variable length field within the question node? Will this present a problem when processing results data?
- Can we eliminate the Account# table and leverage off the account entity table, simplifying our overall schema?
- Account Entity – Maintains account hierarchy, includes support for
 - Patient
 - Group
- Dialog Editor / Composer
 - Enables the creation and maintenance of non-personalized dialogs within libraries, dialog labeling, and import/export capability to the application server database

Issues

Issue	Solution
How to move Content & Results, etc. between systems with different RECNUM links.	Establish Globally Unique Ids for each object that must be moved.
Program Sharing	

Health Buddy Database (BDB)

Health Buddy Databases (BDBs) are the generic term for XML data transported between system components. BDBs are organized as miniature relational databases, enabling rich content, results, and box control information to interchangeably move between Application Servers and Appliances. Also, by utilizing standard XML, foreign systems will ultimately parse and process the information contained within HHN's systems.

Previously, survey content had to be written into script language code and compiled. BDBs remove byte-code overhead, reducing communications expense, and allowing the content to be manipulated as data, even by systems that don't support our VM. A script application can open a content BDB and present sessions in varying ways, depending on patient requirements. For example, patients with poor eyesight might be presented content in a larger font.

A generic Document Type Definition (DTD) is defined for all HHN BDBs. Specific formats for content, results, etc. are defined for each required type of data.

Initially, C code libraries will enable the data-center and appliances to parse and manipulate BDB data. Later, equivalent Java libraries will be written.

Appliance Requirements

- Standard XML with BDB DTD
- Support Multiple Tables - Simple RDBMS style
- Support 32 bit Signed Integers, Date/Time stamps, and Variable length binary strings
- Date/Time stamps encoded using 32 bit Integers in Unix format
- Support Auto-Increment Integer Type
- Self-contained for transmission between systems
- Compactable for efficient transmission between systems
- Must utilize memory efficiently
- Appliance code must be small
- C & Java must be able to work with same format
- Fast storage and retrieval of field values
- Basic Schema info - Table and Field names - embedded in data
- BDB and Content Format versions
- Ability to upgrade library code, enabling shared content in a multi-threaded environment
- Consider explicit One-To-Many record linking mechanism
- Arbitrary Indexing for efficient reporting (Temp & Perm)

Required BDB Appliance Formats

- Dialog
- Patient Info
- Patient Program Cube
- Session Schedule
- Raw Dialog Session Results
- Box Control
- Error Log

Implementation Notes

A uniform API will be developed in both C and Java. The in-memory format for BDBs will not be the same as the transport format. However, this will be hidden behind an opaque API. All BDBs will be freely convertible between internal appliance and XML format.

Initial API

This is a current list of API functions/methods for the C implementation. Note: This design has not been finalized.

Init_BDB, Create_BDB, Destroy_bdb
open_bdb, close_bdb, debug_print_bdb
create_index, delete_index, get_index_count, select_index
add_field, get_field_count, get_field_type, get_field_name
get_record_count, new_record, modify_record, commit_record,
abort_record
first_record, last_record, next_record, prev_record
get_numeric_data, set_numeric_data
get_string_data_length, get_string_data, get_substring_data,
get_string_data_malloc, put_string_data, put_substring_data
find_record_numeric, find_record_string

Questions

- Should we have a global DTD and separate DTDs for each object?

Cube Object

Cube Objects are responsible for maintaining patient state throughout the life of a program. Metrics are stored within the cube and organized by Aspect of Care, Expression, and Date/Time recorded. Typical Aspects of care for a diabetes program might be Foot Care, Eye Care, Blood Glucose Management, and meter Data. Expressions include Behavior, Signs & Symptoms, and Knowledge. Additional expressions may be added to the system later on. Several different types of data are maintained within Cube objects: System and Program Variables, Refined Output Data, and Meter Readings. Cube objects manifest themselves in different ways throughout the system. They are kept in part of the application server database, travel to appliances wrapped inside a BDB, and are maintained in summary within each appliance. Internal formats for Cube objects are based on a relational database model.

Requirements

- Stores metrics by Aspect of Care and expression
- Standard risk level metrics with values: Unknown, (1-3) Low Risk, (4-6) Medium Risk, and (7-9) High Risk
- Tag the Metric with a session/dialog reference so that we can trace-back to the info that generated the metric
- Data Types
 - Raw Response Data linked to metrics
 - Refined Data from Output Nodes
 - Meter readings
- Implementation format must be efficient for common reporting requirements

Implementation Notes

Issues

Dialog Object

Dialog objects are similar to sub-surveys that interact with patients, take meter readings, calculate metrics, and update each patient's cube state. They are kept as generic templates within a common pool, organized by library, inside an Application Server Database. Various parts of the Application Server Schema refer to dialogs in the pool, specializing them by maintaining a list of tags. Dialog objects are transported between application servers and appliances wrapped up in BDBs. All data generated by Dialogs are written to Response BDBs and Cube BDBs. A summary version of each patient's cube is maintained within the appliance, allowing access to cube and response data from within dialogs. This mechanism is the only way for dialogs to share and pass data.

Dialog objects are composed of Interaction, Evaluation, and Mapping sections. The interaction section consists of questions and branching decisions. The evaluation section contains a list of mathematical expressions that evaluate to metric values in the cube. The mapping section links each mathematical expression in the evaluation section to one or more metric addresses in the cube. Each map link specifies an Aspect of Care and Expression.

– Interacts with patients and provides output to update cube state

Requirements

- Dialog nodes (Puzzle Pieces)
 - Question / Answer (Response) – Standard input methods: Short, Long, Multiple Choice, Prompt, ... Note: There are two flavors of question puzzle pieces – Start Question and Followup Question. Only the Start Question is anchored on the work area.
 - Prompt – Stops and provides text info for the patient
 - Output – Writes output to a patient's cube – composed of a metric calculation section and a destination map into the patient's cube
 - Decision – Allows branching based on expressions
 - Calculation – Calculates a value using raw response, cube, and mathematical expressions
 - Goto – Jumps to a label piece
 - Label – Provides a target address for goto's
 - Stop – Halts execution of a given dialog.
 - Meter – Stops execution and takes a meter reading
- Properties
 - Name – Each dialog is named and is referred by name in various parts of the system
 - Library – Each dialog belongs to a global library
 - Tags – Tags indicate special properties
 - Default Scheduling frequency
 - Default Reporting status
 - Last date/time executed
- Localization versions within Dialog Object

Appliance

Appliance Summary

The appliance requires additional functionality in order to support the FlexCube architecture. A To Do List architecture opens up the appliance for many-to-many communications and enables multiple users on an appliance and multiple programs or content sources per user. Content, Results, E-Commerce Transactions, User and Appliance information will all be transported as BDB XML.

Requirements

- To Do list architecture
- XML / BDB content, results, e-commerce, user and appliance information
- New system applications

Appliance Applications – To Do List Architecture

Initially, appliance code will be written in C/C++. Later, an enhanced scripting language/VM will enable the applications to be written in our scripting language. These scripts will be responsible for managing the overall box behavior. Responsibilities include Scheduling and handling appliance communications, presenting content, etc.

Requirements

- Box Manager Application
- Communications Application – Overall responsibility for non-conversational communications
- Connection Application – Brings up the physical communications link
- Login Application – Logs in and establishes a secure connection
- Mail Exchange Application
- Session Application
- Presenter Application

Box Manager Application

The Box Manager Application waits for one of two events to occur. When it's time to call into the data center, the Box Manager calls the Communications Manager and exchanges content, results, etc. Whenever a button is pushed on the appliance, it calls the Login application to initiate sessions and allow patients to initiate sessions. While it is idling, it may indicate content availability and check system integrity.

Requirements

- Handles call-in schedule (Box hardwired with call-back failsafe)
- Calls Communications Manager
- Calls User Login Manager
- Calls Session Script upon user authentication
- Schedules Results BDB for delivery to application server

User Authentication / Login Manager

- User BDB enables/disables user login requirement and style
- Styles
 - Select User from List
 - Authenticate via Luggage Lock (Clapp's method)
 - Authenticate via Smart Card
 - Authenticate via PIN

Communications Manager

Requirements

- Calls Connection Manager
- Calls Login Manager
- Calls Mail Exchange Manager
- Returns success/failure.

Connection Manager

The Connection Application will be responsible for dialing into our service provider (ISP or EDS) and establishing the physical communications link. BDBs will provide a prioritized list of local connection numbers. A fallback 800 number will dial back to HHN whenever the local connections are unavailable.

Requirements

- Brings up the physical communications link
- 800 Number for Fallback
- Prioritized list of local numbers

Login Manager

The Login Application is called after a physical link has been established. This application is responsible for logging into the host system, authenticating the box, establishing a secure connection, and navigating to the proper host service prior to data exchange. The scripts and other required information will be embedded in BDBs.

Requirements

- Logs into host system
- Authenticates box
- Establishes secure connection
- Navigates prior to data exchange

Mail Exchange Manager

Requirements

- Retrieves new content and message BDBs
- Uploads new results and message BDBs
- Uses SMTP & POP3 protocols
- Will likely use non-standard ports to promote security

Session Manager

The Session Application provides the To Do list functionality for multiple content types. Initially, FlexCube content will be the primary content.

Requirements

- Calls FlexCube Presenter Application to execute content BDBs
- Prioritized with Round-Robin resolution.
- Do not present until time/date property
- Expire after time/date property
- Required Flag (This must be run before any lower priority content BDBs can execute)

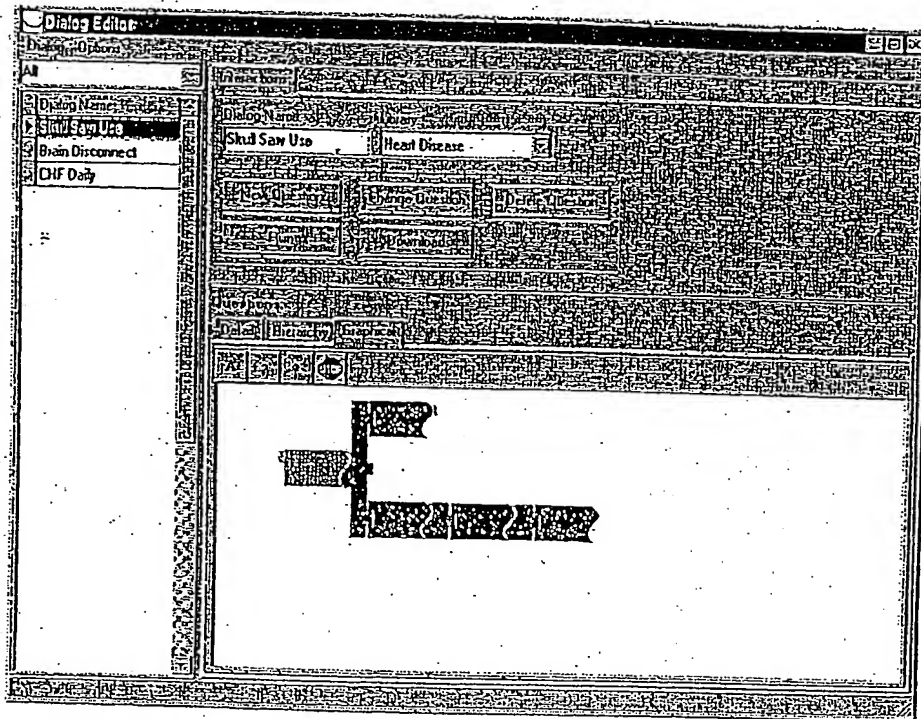
FlexCube Presenter Application

The Presenter Application is responsible for presenting FlexCube content to the patients.

Requirements

- Presents content packaged in BDBs to patients
- Writes raw question responses and evaluations to a BDB
- Updates Box cube state
- Supports standard input methods

Windows GUI Applications



Dialog Editor

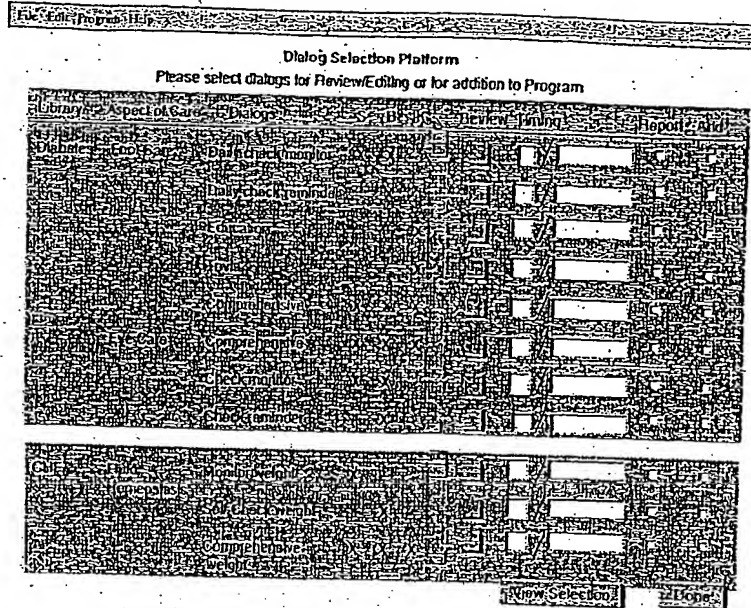
The Dialog Editor application is the primary tool for content development.

Requirements

Requirements

- Experience Levels
 - Beginner View – Holds author's hands, but doesn't allow full use of system
 - Expert View – Enables all features, expects author to fully understand system
- Editor Views
 - Graphical Editing view
 - Hierarchy view
 - List view
- Segregate Dialog Pool into libraries
- Select Default Dialog Properties
 - Name – Each dialog is named and is referred by name in various parts of the system
 - Library – Each dialog belongs to a global library
 - Tags – Tags indicate special properties
 - Default Scheduling frequency
 - Default Reporting status

Program Selector



Program Selector is the application that enables Care Managers to build programs by selecting a set of dialogs from the system pool.

Requirements

- View/Select available dialogs by
 - Library
 - Body System Tag
 - Name
- Set Program Properties
 - Start and End Dates
 - Inclusion and Exclusion weekdays, dates, and date ranges
 - Default Reporting Status

Program Linker

File Edit Program Help

Patient Selection

Custom Grouping

DOB

Print

Patient List

Name	Original Link(s)
Andersch, Aaron	ABE
Brockow, William	
Cutzman, Bill	
Denzon, Dan	
Erlson, Eric	
Fatman, Fred	
Gilroy, Gillian	
Hansen, Hans	
Ingenhoul, Irene	
Jensen, Erik	

Client Program Link

Code	Program Name	Review
A	Care Mgmt.	Kaiser CHF/DM
B	Education	Foot Care Tips
C	Utility	Greetings
D	Utility	Satisfaction
E	Utility	Personal Mail
F	Utility	Weather/News
G	Utility	SF38

Program Linker is the application that links and unlinks patients and programs. This application also enables Care Managers to set program parameters on a patient by patient basis.

Requirements

- Link/Unlink an arbitrary list of patients into or out of an arbitrary list of programs
- Set patient specific program properties
 - Start / Stop dates
 - Include / Exclude specific weekdays
 - Include / Exclude specific dates and date ranges
 - Select and Approve Patient Risk Levels
- Select/Deselect patients using standard Windows GUI
 - All
 - Range
 - Individual Select/Deselect
- Sort List by
 - Name
 - Date of Birth
 - Risk Profile
 - Custom

Session Scheduler

Session scheduler is the application responsible for scheduling and managing content presentations on the appliance. It can run as either an automatic engine or as an interactive utility. It is also useful for reviewing and editing session data.

Initially, Session Scheduler will run in semi-automatic mode. Care Managers will be able to select a patient / program combination and then view the scheduled sessions. Filter control will be provided.

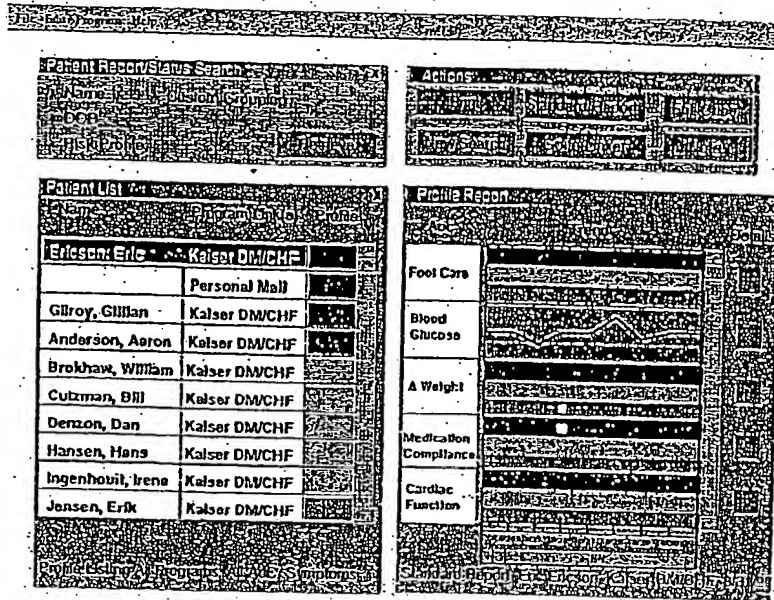
Requirements

- Manual and Semi-Automatic Session generation
- Ability to view and edit listed sessions
- Session status indication – Generated, Deployed, and Completed
- Session Boundaries
 - Dialogs prioritized within a session
 - Limit on total dialogs in a session
 - Dialogs selected based on individual cube state
 - Dialogs selected based on program frequency
 - Round-Robin Dialog selection for equivalent dialogs
 - Greeting dialogs with highest priority
 - Exit dialogs with lowest priority
 - Must Execute Flag – This dialog must execute without allowing patient choice before lower priority sessions are presented as to-do items
 - Inclusion / Exclusion periods for patients – blackout a vacation period
- Intelligent Session Deployment
- Initially, Care Managers will be required to approve sessions

Future

- Support for Population Session creation and scheduling
- Fully Automatic Session generation

Reporter



Reporter is the primary application for reviewing patient results and status as well as paper reports. The first suite will be written as a fat client. Later, much of Reporter will be duplicated using a thin-client HTML only model.

Requirements

- High Level Patient View
- Clickable Human Body in patient detail view
- Patient Summary Report
- Population Summary Report
- Raw dialog results viewer
- Report generation summarized by hierarchy

Administrator

Administrator is the application that manages overall system operation and configuration.

Requirements

- Account Entry / Maintenance / Status Changes
- Patient Entry / Maintenance / Status Changes
- Copy Programs between Account Entities
- System Config, Patient Entry, Account Entry

Future Additions

Enhanced Scripting Language

The scripting language will be enhanced in several areas with the addition of structures, BDB manipulation statements, and communications operations. Structures are collections of simple variables, much like a form. Structures make it possible to manipulate data extracted from a BDB as records. Scripts will be able to open BDBs and manipulate data. New communications functions will allow scripts to communicate with other systems using the modem or serial port.

Requirements

- Structures passed by value into functions
- Structures must support existing primitive types: 32bit Signed Integers & Variable length binary strings
- Full HAL functionality
- Serial & Modem communications support
- Date & Time types

Thin-Client Applications

A production version of the system needs to supply a thin-client web view for checking patients, scheduling content, and basic system functions.

Thin Client Features

- Universal access via HTML browser to the system over the internet
- Global Access to data
- Eliminates deployment issues

Questions

- In the first prototype, should we aim to create sessions on a program basis, patient basis, or both? (Patient Basis First)
- Should we build a schema capable of multiple accounts? (YES)
- Can we really merge raw data into the cube? (Probably, but it would be more efficient to store separately)
- Should a patient have a cube for each program?

Thoughts / Issues

- We need to support shared puzzle-pieces
- Maybe have a Global AoC for things like HMO procedure approval screens: Your responses indicate physician attention is required, please call Dr. Smith if you do not receive a call from your doctor by tomorrow...
- Need easy way to leverage into thin-client
- Can we ask Mitch to include us in core-engineering discussions
- Wizards
- GUI hand-holding methods – Help, etc...
- Sharing of Dialogs between accounts
- Moving data between data-centers
- Dialog Interaction Precaution Tags
- Dialogs that refer to outside AoCs
- Development Hardware
- Investigate DB2

Input

- 8/23/99 - All new patients get tossed into a special group "New Patients(5)" to make it easier for CMs to put into programs. Avoid one big pile of patients where you can't tell who is new, etc...

Albert Schema Questions

- Many to many on Patient / Account Entity
- How do we move data between DBs? I'm sure this problem has been solved before in various ways. But, we need to figure out how. One thing I think we can do is integrate account # into the XML that we send. Even if it's not part of a given table. This may assist in reassembling the relationships at the destination. Another note: Account#s must be globally unique between all data centers.

To Purchase

- DBA Tool(s)
- VMWare
- Order Oracle? (v 8.03/8.04 issues – CB4 Driver requires a version higher than we have...)

System Features / Requirements

- Hidden AoCs within Cube
- Escalations

Escalations

Minimal time and effort required to manage content

Glossary

- Application Server** – Computer system including appliance communications and thin-client web front-end and a database of content, patients, account entities, scheduling, and results.
- Aspect of Care (AoC)** – A topic within the Cube Object. Aspects of care for a diabetes program might be Foot Care, Eye Care, Blood Glucose Management, and One-Touch BG Meter.
- BDB** – A micro database object that moves cube content, dialogs, and raw response information to and from the appliance. BDBs travel in XML form.
- Database Schema** – Stores dialog and program content
- Cube Object** – Stores patient state. Includes Raw Response Data, Refined Patient Data, and Meter Data.
- Dialog Editor / Composer** – An application for creating and maintaining non-personalized dialogs within the Dialog Pool in an Application Server.
- Dialog Node** – An executable object within a dialog. These correspond to the puzzle-pieces in graphical view. Examples include: Question, Output, Goto...
- Dialog Object** – Interacts with patients and provides output to update cube state
- Dialog Pool** – The section of an Application Server that contains content dialog objects.
- Expression** – A subtopic within the Cube Object. Expressions are typically Signs & Symptoms, Behavior, and Knowledge.
- Globally Unique ID** – Unique identifiers for patients and other database objects, enabling data portability and aggregation.
- Library** – The dialog pool is partitioned into libraries. An attribute of a dialog. Typical libraries might be Diabetes, CHF, or Utilities
- Localization** – The ability of a system to support non-English languages
- Metric** – A measurement, most metrics are risk levels or meter readings. The third axis of the cube
- Personalizer** – Maintains patient-specific cube metrics, defining risk levels, etc.
- Program Selector** – Selects dialogs from libraries in and out of content specific programs, specifies labels for scheduling and reporting
- Puzzle Pieces** – A reference to the graphical objects in the dialog editor. Puzzle pieces include: Start Question, Followup Question, Prompt, Output, Decision, Calculation, Goto, Label, Stop, and Meter.
- Reporter** – Patient results lookup organized into levels from patient-specific program overview to raw results from particular session, including graphical body system view.
- Schema** – A database design, specifying the data stored and relationships between different parts of the database
- Script** – Byte code used to implement appliance applications and evaluate expressions within a dialog
- Session Application Script** – This is a compiled byte-code program that presents content to a patient. In FlexCube, this application will present dialogs and manage cube-state within the appliance as well as manage synchronization between the appliance and data center.
- Session Scheduler** – Semi-automatic creation and scheduling of patient specific sessions
- SuperNova** – An archive and distribution infrastructure for HHN system components. FlexCube is the data. SuperNova is the highway.
- Tag** – An attribute associated with a given dialog / patient or dialog / program. A typical tag might be presentation frequency.
- XML** – A text based format for encapsulating and transporting data between systems. The generic format used for HHN's data is called a Buddy Database (BDB). Acronym for Extensible Markup Language.

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APPENDIX B

Consumer Applications: Long Distance Care High-Level Requirements and Design

DRAFT

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1 Vision

The vision of the consumer applications effort is to provide applications outside the core HHN/VOLS that extend the definition of the care manager and grow the HHN business into the consumer-related areas. These areas are in the health care information technology arena, but are driven by consumers and not by a hospital or HMO. Applications currently under consideration involve partnerships with:

- caregiver.com – Long Distance Care
- Stadlanders – Care Management of Stadlanders (medication) customers
- Weight Watchers – Management of people in Weight Watchers programs

1.1 Vision for Long Distance Care

The largest group of care managers in this country are family members taking care of aging parents and relatives. Family care giving has traditionally been a role of women in their 40's and 50's. Many of these women are now baby boomers in the workforce. Also, the mobility of the baby boom generation has resulted in many children living far away from their aging parents and other aging family members as well. These two trends have helped create an opportunity for technology-enabled, remote care management of elder relatives by baby boomer children.

1.2 Documentation

This document includes materials from the following documents that have been produced within HHN:

- HHN LDC Preliminary HLRD.doc
- Informal Caregiver Requirements.doc
- Informal Caregiver Requirements.doc
- cg pricing.xls
- Term Sheet for Careguide.doc

2 Scope

The scope of this project is an application built around long distance care. The Health Hero Network Long Distance Care Service (HHN/LDC) is envisaged as a value-added service to the HHN/OLS that enables care providers such as family members to check on relatives in assisted living facilities. The relatives would each have a Health Buddy, and the HHN customers would access information via a thin web client.

HHN/LDC would tie into the HHN/OLS to communicate with the people in assisted living facilities who would answer daily dialogs by using the Health Buddy. The customer would create personalized content for the family member, be informed of certain alert situations, and receive reports on the family member's status.

The HHN/LDC application is in the concept stage and is currently being discussed with Careguide.com. This document represents HHN Software Products' preliminary understanding of the application based on input from Steve Brown, HHN marketing, and HHN clinical and provides a summary of high-level requirements and a high-level design for the HHN/LDC application.

2.1 The Market

10 million seniors live alone, and 2 million seniors live in assisted living facilities. The numbers are growing rapidly because of the aging population. While this drives the care management and assisted living businesses, it is also creating huge unmet needs for family members.

HHN has test marketed the concept of an internet based service that would allow family members to monitor parents with a Health Buddy, combining personal messages with canned senior wellness dialogues and web-based reports for the family member. The initial discussions included about a dozen working women who were in their 40s and 50s, were computer users, and were worried about aging parents. Every one expressed an interest in paying out of pocket for such a service "in a heartbeat." HHN has also introduced the idea to three major employers accounting for more than 75,000 employees. Two of these employers expressed an interest in offering such a service through their Employee Assistance Programs. The price we discussed was \$500 for a one-year subscription.

More formal market analysis may be possible with Careguide.com as they have 1.3 million page views per month from an audience primarily composed of adult children of aging parents resulting in 17,000 referrals to assisted living providers.

2.2 Benefits to customers

The service can benefit the family member in assisted living:

- Stay home longer rather than going to assisted living
- Feel more secure, that someone cares
- Stay in contact with family member

The service can benefit the caregiver:

- Patient stays home longer saving the cost of an assisted living facility
- Provides quality assurance of services for patients already in an assisted living facility
- Reduced stress, improved quality of life for the patient and the care giver

2.3 Benefits to HHN

- Huge market opportunity potentially in the hundreds of thousands.
- Higher price possible
- Consumer private pay over the web means less contracting issues
- More control over network for future services such as e-commerce
- Additional market exposure for the Health Buddy concept

Putting Health Buddies into the consumer marketplace would expand the awareness of the Health Buddy to potential users of other HHN services. For example, people purchasing the HHN/LDC service might also be diabetics or have other family members who are diabetic. There are also many upselling opportunities e.g. HHN/LDC users might be interested in hearing about lightweight, warm robes and blankets that can be shipped to a loved one.

3 User Scenarios

3.1 Sign up/enrollment

Kate is a 40-year-old businesswoman and mother of three who lives in San Francisco. Her mother is 85 years old and has just moved into an assisted living facility, as she can no longer take care of her home by herself. Mrs. Novitsky takes several medications on a daily basis, is occasionally forgetful, and generally feels somewhat isolated and lonely.

Kate has used Careguide.com to find and select her mother's facility and remembers seeing something about a Health Hero service, she goes back to find out more about the service. After reading the description and seeing how the Health Buddy works she is ready to sign up for her mother.

Kate completes the registration questionnaire providing her contact information as well as demographic information about her mother. She closely reviews the Health Hero services agreement and acknowledges her acceptance of the agreement. She then proceeds to enter her credit card information to finalize her request for enrolling her mother in the Health Hero program.

Kate is now on the Health Hero program home page and sees that she can personalize the program to meet her mother's needs. She quickly moves through the step by step personalization wizard and enrolls her mother in a medication compliance and wellness program. As part of the medication program setup, she is prompted for information about her mother's medications. Kate is asked if she would like to receive a special alert via fax, e-mail, or pager if her mother's responses indicate that she is not taking her medications or is in need of a refill. Kate has no idea how critical this medication is so she clicks on a link that takes her to a detailed description of the medication. There she learns that this medication is very important, so returns to the program set up and selects to receive an alert via e-mail.

She then requests a birthday message for her mom's birthday on Feb 5th and a special "thinking of you" message for the anniversary of her father's death. Finally, she enters a personal greeting message to be delivered to her mother as part of the first set of dialogues.

Kate decides to accept the default set of reports and has now completed enrolling her mother in the Health Hero program. She calls her mother to tell her the good news.

Within moments of completing her enrollment, an e-mail is sent to Kate to welcome her to the program and confirm her mother's enrollment. A Health Buddy transaction is also generated to FedEx.

As FedEx ships the Health Buddy, another e-mail is sent to Kate to let her know that the Health Buddy is being delivered to her mother.

3.2 Program Delivery

Mrs. Novitsky has no problem following the Health Buddy's setup instructions and is excited to receive her first communication, which starts with the personal greeting from her daughter.

She dutifully responds to the questions for the first two days and anxiously awaits another message from her busy daughter. On the third day she indicates that she has run out of her blood pressure medication. This causes an e-mail to be immediately generated and sent to her daughter. Kate calls her mother to find out what the issue is. Mrs. Novitsky could not get a ride to the pharmacy to refill her prescription, so Kate calls the pharmacy and arranges to have the prescription delivered.

As time goes by, Kate has established a routine of logging into the Health Hero service weekly to review her mother's results, and entering new personal messages to be delivered during the week.

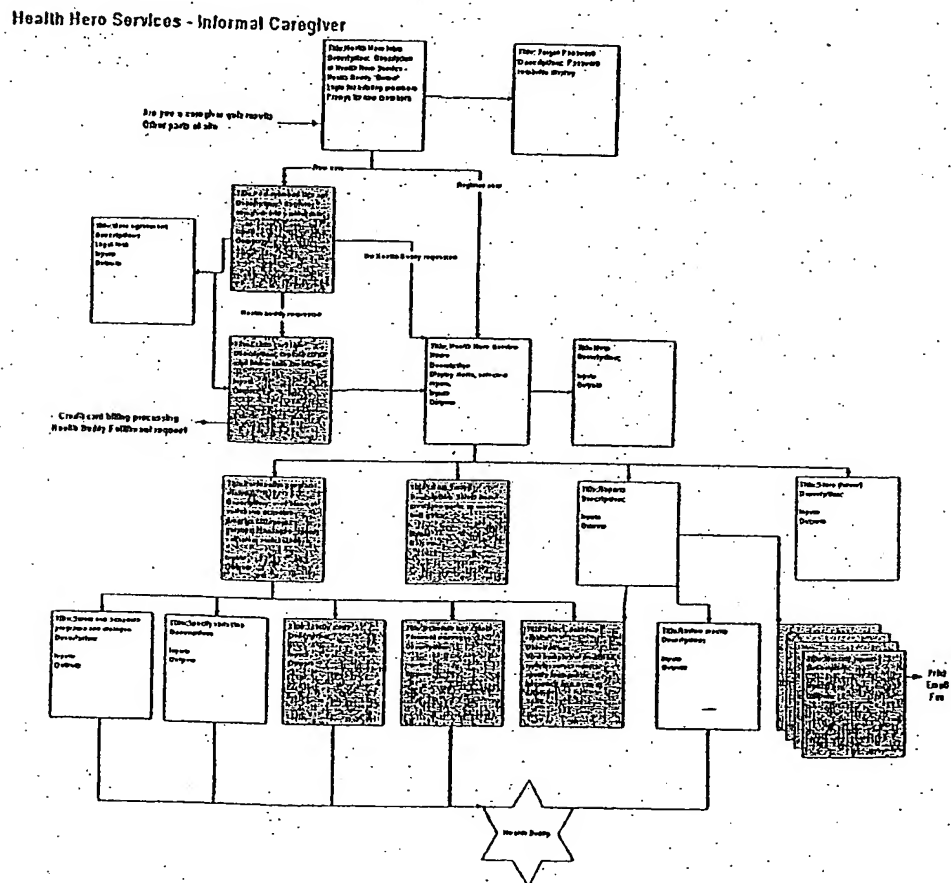
During a regular conversation with her mother, Kate learns that Mrs. Novitsky has a regular appointment with her physician coming up next week. Kate logs into the Health Hero service and requests that a copy of her mother's reports be faxed to the doctor's office for his review.

At the end of the doctor's visit, the office staff e-mails Kate that her mother is doing fine but could use some help in managing her nutrition. Kate logs into the Health Hero Service and enrolls her mother in a nutrition program, specifies her mother's ideal weight, sets an alert to occur if she loses more than five pounds in a week. Finally, she selects a link to a site that delivers groceries where she orders a regular delivery of groceries to her mom.

4 High-Level Requirements

This section contains high-level requirements received from marketing. These requirements currently comprise features of the envisaged service.

4.1 Workflow diagram



4.2 Health Hero Services Introduction/Splash Page

This web page will contain an introduction to the Health Hero Service and a demonstration of a Health Buddy communication. The goal is to get caregivers to sign up for the service. Specific features are:

- Prompt for user login/password
- Prompt for New User sign-up
- Forgotten password assistance
- Links to individual program descriptions
- Links to program enrollment checklists (information needed to complete enrollment for individual programs)

4.3 Member Sign Up

This section will allow the caregiver/purchaser to sign up and activate the HHN/LDC service. Specific features are:

Member Registration

- Caregiver/purchaser information – demographic, contact, login and password setup
- Health Buddy user information – demographic, contact
- User can register but not activate/request health buddy
- Sign up for a Health Buddy e-mail newsletter (generated and distributed by Health Hero)
- Send follow-up confirmation e-mail for new registrants
- Send notification letter to patient

Activation/deactivation/upgrades/bundled medical devices

- Allows caregiver to turn on service
- Allows caregiver to cancel service
- Allows caregiver to purchase upgrade services (i.e. BuddyLink, etc) – future requirement

Billing information

- Credit card information

Health Buddy Information

- User entered information – user specific set up information
- Additional optional patient information – medications, diagnosis, physician etc.
- Health Hero maintained information (or Interface from FedEx) - Health Buddy serial number, ship date (In the future this may be other device information)

- Interface to FedEx for Health Buddy Fulfillment
- Notification of shipment e-mail to caregiver from FedEx

User agreement

- Legal agreement/disclaimer
- Caregiver/purchaser acceptance of agreement
- Patient agreement will be achieved through a dialogue on Health Buddy

4.4 Credit Card Billing

This component handles the financial transaction between HHN and the purchaser of the service. Specific features are:

Verify credit card

- Interface to service for automatic credit card verification/validation

Credit card billing transaction

- Link to e-commerce server

4.5 Personalize Program - Wizard for Content Selection and Scheduling

This component provides a step-by-step user interface that walks the caregiver/purchaser through the process of setting up and changing programs and dialogues for a Health Buddy user. Specific features are:

Select and schedule program and dialogues from available library

- Select from a list of programs and dialogues defined by Health Hero staff, using existing Composer functionality. Examples of preloaded content are:
 - Nutritional status (e.g. weight, appetite)
 - Medication compliance
 - Regular (e.g. monthly) assessment tools
- Enter program-specific Health Buddy user information
- Link to resources (ie Drug information, 'health handbook' etc)

Schedule and create personal messages

- Short message from informal caregiver to patient
- Appended to scheduled dialogue

- Message scheduled for a specific calendar day or a day of week (i.e. one time only or repeating) or to be delivered in the next communication

Schedule and create sponsor messages/dialogues

- Sponsor may be Careguide.com, Weight Watchers, or other third party
- Caregiver option (on behalf of patient) to receive or not receive sponsor messages
- Dialogues created by Health Hero using existing composer functionality
- Dialogues or messages assigned and scheduled by Health Hero
- Dialogues or messages appended to consumer-scheduled dialogues/messages

Specify variables

- Enter patient specific values for default variables previously defined in Composer by Health Hero staff

4.6 Personalize Reporting and Alerting Wizard

This component provides a step-by-step user interface that walks the caregiver/purchaser through the process of setting up and choosing reports and alerts. Specific features are:

Specify alerts

- Select alerts from predefined list. Examples might include:
 - Non-response for specifiable (e.g. 3) number of days
 - Significant (specifiable e.g. 5 lbs) change in weight
 - Request from family member for a phone call
 - Medication non-compliance (specifiable e.g. more than 3 missed doses per week)
- Specify when and how to receive alerts
 - Displayed on Health Hero Services Home Page (within Careguide.com)
 - E-mail

Specify reports

- Select from predefined list of reports. Examples might include:
 - Nutritional status and weight tracking report
 - Medication compliance report
 - Reports from assessment tools
- Option to preview a sample of report
- Specify report recipients
- Specify report delivery mode – fax, e-mail, display on-line

- Specify report frequency – daily, weekly, monthly, quarterly

4.7 Viewing Status and Reports

The caregiver/purchaser will have a personalized Health Hero Services Home Page. This will allow the purchaser to view:

- Alert messages
- Program summary
- Sponsor or Health Hero messages to caregiver/purchaser
- Links to careguide (or other sponsor) web pages/content
- Caregiver-selected reports with fax/e-mail/print/view on-line options
 - To physician
 - Other care manager
 - Others

4.8 Help

Help for the customer will include:

- On-line FAQ accessible via Health Hero services home page
- On-line documentation

4.9 Customer Service

On-line e-mail

- Health Hero support staff respond within 24 hours

Telephone

- Health Hero staff for "use of service questions"
- Call center partner for clinical/health related questions

4.10 Long Distance Care Program Content

The Long Distance Care program could include:

Program Content	Personalized Content	Reports
Nutritional Status (weight, appetite, etc.) Wellness Rating Scale Medication Compliance Monthly Assessment Tool <ul style="list-style-type: none"> • Quality of Life Tool • ADL • IADL • Safety • Depression • Mini Mental Status Exam Personal Hygiene Skin Care Nail Care (Podiatry) Sleep Safety Nutritional Needs Primary, Secondary and Tertiary Care Loss and Coping Social Support Urinary Incontinence Bowel Function Activity Financial Status Barriers to Compliance Tip of the Day Trivia Motivational	Personal Messaging Scheduled (i.e.: Birthday) Reminder Service Personal Variables Personal Goals	Alerts <ul style="list-style-type: none"> • Non Responders • Significant Change in Weight • Significant Change in Wellness Rating • Medication Non Compliance • Request for a Call • Individually Selected Key Indicators Monthly Reports <ul style="list-style-type: none"> • Individually Selected Variables • Statement of Nutritional Status • Report of Medication Compliance • Monthly Assessment Tool Findings • Acknowledgement and Affirmation of Status

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Up-Selling Opportunities

Financial Planning

Books

Long Term Care Facilities

Pharmacies

Webvan.com

Support Groups

Medical Support

Durable Medical Equipment

Insurance

Long Term Care Planning

Safety Products

Drug Stores

Card Game Sites

Travel

Online Shopping

5 High-Level Design

The currently envisaged design is a simple thin client web interface for the family member that connects to the current middleware and database for scheduling content and manages results from Health Buddies. The thin client web interface is simpler alternative to the care applets. Since there is limited composing of surveys, much of the Care Composer is not required by the purchaser/caregiver. Content will be created by HHN or the service provider and not by the purchaser/caregiver. Also, since little of the care manager functionality is required, much of the Care Director and Care Administrator is not required.

The subscriber will view everything via a web page interface, with the possibility that applets might be used in cases where more user interaction is needed, e.g. the scheduling interface. The main idea is to keep things simple for the subscriber.

The HHN/OLS v2.0 architecture currently under discussion includes migration of some functionality to a thin-client web interface and this is highly consistent with the requirements for HHN/LDC. As such, work on HHN/LDC and HHN/OLS v2.0 need to be synchronized.

5.1 User Interface

The user interface is determined by the actions that the subscriber needs to perform. The key actions of the family member caregiver in the HHN/LDC service are described below.

Signing in to the LDC program: These screens allow entry of current users to secure locations and provide information on the program to new users that encourages them to subscribe to the LDC service.

APPLICATION CONTENT	CONTROL	VALIDATION/RULE	DESCRIPTION
Login dialog	form		Includes: <ul style="list-style-type: none"> • username/password input boxes • new user link – loads form to collect information on new user • forgot password link – loads form with instructions for calling to get password • program descriptions link – loads form with descriptions of available programs • program enrollment link – loads form to capture information necessary for enrollment in individual programs

Signing up to the LDC program. These screens should include capture of data re the caregiver and the patient that enable shipping of a Health Buddy to the patient. The screens should accept the family member's credit card as payment for the program. The credit card billing infrastructure will require a link into an e-commerce server.

APPLICATION CONTENT	CONTROL	VALIDATION/RULE	DESCRIPTION
Caregiver/purchaser Information	Form	Confirmation e-mail is sent to new caregivers.	The caregivers demographic, contact, login and password setup information is captured. Caregivers can optionally subscribe to newsletter.
Health Buddy user information	Form	Notification letter is sent to patient.	The Health Buddy users demographic and contact information is captured. Optional information e.g. pt medications, physician, is captured.
Health Buddy User Agreement	Health Buddy dialogue		Legal agreement obtained via Health Buddy dialogue.
Activation	Form		Allows caregiver to turn on, cancel or upgrade service.
User Agreement	Form	Caregiver acceptance of agreement required to move on.	Legal agreement, disclaimer is loaded.
Billing			Credit card information captured. Verification and validation achieved via interface to service. Transaction logged via eCommerce server.
Fulfillment	Form	FedEx EDI interaction completed and e-mailed from FedEx to caregiver generated.	Captures information necessary for FedEx EDI transactions.

Choosing LDC preloaded program, creating personalized messages and scheduling preloaded and personalized dialogues. These screens should allow the family member to:

- Select an LDC program and dialogues based on content that are available in the (content) database.
- Create a message (prompt) that can be scheduled to play on the Health Buddy on a specific date. These personalized messages can be stored using the patient variables structure.
- Schedule selected content. This should look like a calendar that is populated based on what LDC preloaded program is chosen and what personalized messages are created. The calendar should be editable. The scheduler/calendar may need to be an applet in order to offer the required functionality. Scheduling using the current architecture is a major issue. Please see the section describing some of the issues.

APPLICATION CONTENT	CONTROL	VALIDATION/RULE	DESCRIPTION
LDC Program	Form		Select LDC program(s) e.g. <ul style="list-style-type: none"> • Nutritional status • Medication compliance • Regular assessment tools

APPLICATION CONTENT	CONTROL	VALIDATION/RULE	DESCRIPTION
LDC Messages	Form		Create messages for scheduling with LDC program dialogues
Schedule Calendar	Form		Schedule LDC program content with appended, personalized messages for delivery via Health Buddy. Can be edited.
Resources	Form		Links to available Health Care Resources i.e. Drug Information, "health handbook", etc.
Sponsor Messages	Form		Caregiver can elect to not have sponsor messages show up to patient *(see sponsor below)
Variables	Form		Allows caregiver to enter pt-specific values instead of defaults set by HHN.

Choosing, scheduling, and viewing reports. These screens will provide a web interface for a report menu where previously created reports can be viewed, reports can be run, and reports can be scheduled to run at defined times. The reporting will require a report server on the back end as an additional piece of architecture.

APPLICATION CONTENT	CONTROL	VALIDATION/RULE	DESCRIPTION
Alert Select	Form		Select Alerts from pre-defined list. Specify how to receive alerts: e-mail, web.
Report Select	Form		Select Reports from pre-defined list. Option to preview reports.
Report Delivery	Form		Specify report recipients, delivery mode and frequency.
Alert and Report Viewing	Form		Viewing options include <ul style="list-style-type: none"> Alerts Program summary Sponsor or Health Hero messages to caregiver Links to careguide (or other sponsor) web pages/content Caregiver-selected reports with fax/e-mail/print/view on-line options

***Creating/scheduling sponsor messages/dialogues.** These screens should allow for creation and scheduling of sponsor messages. This may be a screen in a separate wizard that can be run by the sponsor (i.e. Careguide.com or other third party), or created by Health Hero using existing composer functionality.

APPLICATION CONTENT	CONTROL	VALIDATION/RULE	DESCRIPTION
LDC Program	Form		Select LDC program(s) e.g. <ul style="list-style-type: none"> Nutritional status Medication compliance Regular assessment tools
LDC Messages	Form		Create sponsor messages for scheduling with LDC program dialogues

APPLICATION CONTENT	CONTROL	VALIDATION/RULE	DESCRIPTION
Schedule Calendar	Form		Schedule LDC program content with appended sponsor messages for delivery via Health Buddy. Can be edited.

The design of the user interface will be wizard-like, stepping the caregiver through the above actions. The interface will be web based so that no installation will be required on the client machines.

The user interface will be entirely new. Some of the current screens could be used as models, but most of the interaction that the subscriber will have with the system will be at a simpler level than with the current care managers. The user interface will be simple and easy for a subscriber to walk through and find what they need.

5.2 Server-side changes: Database and Middleware

Based on the requirements for the interface, most of the server-side changes will be in scheduling flexibility and the addition of servers/middleware to handle reporting, alerts, and e-commerce.

The key database and middleware actions in the HHN/LDC service are:

- Construction of surveys from preloaded and personalized dialogues; ready for download to Health Buddy with specific dialogues or on specific dates.
- Handling situation where survey is not answered, i.e. queuing of surveys while allowing for personalized dialogues to run in the box on a given day.
- Modifying surveys that have been constructed and are scheduled, to add further personalized dialogues.
- Scheduling constructed surveys to run on Health Buddy.
- Scheduling reports
- Running reports and returning results to files that are linked to family member web pages.
- Including graphs in reports.
- Handling of role-based security, archiving and distribution of reports.
- Handling alerts.

This database and middleware functionality requires additional middleware to be written for database communication and communication with an additional report server, graphics server and web server. Middleware changes need to be made to allow extra flexibility in scheduling. (Please see scheduling section later).

When reporting from the server, the middleware components interact with the database, the graphics server, the web server, the report server, and the report writer. There are two distinct sets of middleware: those interacting with the web server and those interacting with

the report server to create reports. The components used by the web server assist in creating dynamic web pages for display to the user. The components used by the report server handle the interactions between the graphics server, the database, and the report writer to bring all the pieces together into a completed report.

The middleware components interact with the report writer to construct the reports from database data and from graphical and textual output produced by the graphics server. The middleware controls the creation of ad-hoc reports with help from the report writer's functions. Data may be sent from the middleware or from the database to the graphics server. The middleware connects to the various databases that are supported in the application.

Changes to the current database should be fairly limited. There will be multiple additions however, since the database will have to store additional information, such as credit card data and alert information. A more in-depth review of the requirements will be needed in order to list all of the database additions and changes.

The current middleware can be used with additions and modifications to handle the additional data and the additional server-side components that are required for reporting and e-commerce.

5.3 Application Content

In order for this application to be relevant to a wide patient population, a significant quantity of high-quality content needs to be developed and integrated into the application. Content areas may include:

- Personal hygiene, skin care, nail care, sleep, safety, social support, urinary incontinence, bowel function, activity, financial status, barriers.
- Nutritional status
- Medication compliance

Other key tasks in the content area are:

- Content needs to be arranged to be readily scheduled into marketable programs e.g. monthly, quarterly etc.
- Content needs to be tagged to enable reporting of results.

The pre-defined application content will be created by HHN or the service provider using the Care Composer. The content will be stored, created, and reviewed using the Care Composer. The subscribers might be able to review the content but they will not be able to modify the pre-defined content. Personalized messages can be added to the pre-defined content.

5.4 Survey definition and scheduling

The current dialogue scheduling architecture has two significant problems in the context of HHN/LDC and other applications (e.g. HHN/DMS -Diabetes).

- There is no way to merge content at schedule time
- Only one survey per day can be sent to the Health Buddy

For the HHN/DMS system, we add personalized questions (goals) to pre-loaded surveys (education subtopics) by specifying goals as program metrics. We specify one metric that sets an upper limit on the number of goals allowed and individual metrics for each possible goal. Questions based on these metrics can then be added to each pre-loaded survey (programmatically). These questions act as placeholders for goal questions that may be asked at some point in time.

The architecture described above will work for the HHN/LDC application only if we ensure that some pre-loaded content is sent to the Health Buddy each day. Even then, if questions are not answered on a given day, surveys scheduled for the next day will not be sent on that day. The current architecture thus does not ensure that personalized content scheduled for a specific day will actually run. The best we can do in the current architecture is to allow personalized messages to be appended to dialogues that are part of the program, and for the program dialogue and message appendix to be run in sequence. However there would be no guarantee that a personalized message would appear on a particular day of the year.

Going forward, a more flexible architecture is desired. Features and requirements should include:

- Ability to combine surveys for scheduling on a given day.
- Ability to schedule surveys like appointments e.g. weekly, monthly etc. via a calendar.

The scheduling of personalized content is one area where a lot of work will need to be done to give the flexibility requested in the requirements. There are some workarounds as described above, but the flexibility desired in the requirements would not be completely attainable with the current scheduling and addition of content mechanisms. Note that all additional work on content scheduling would need to be done by, or in conjunction with, the HHN Mountain View Engineering team.

5.5 Reporting

The reporting component is a crucial part of the HHN/LDC. Subscribers need to easily schedule and view reports. The current system does not handle the reporting architecture that will be needed for this system.

The simplest, cleanest approach to reporting is to set up a new report server (with report writer), statistics/graphics server, and a web server. The report server will require middleware for connectivity to the transactional database at EDS and for connectivity with the report writer, statistics/graphics server, and the web server.

Given the current HHN internal processes it would be most efficient for this project (and for the v2.0 core offering) to set up separate boxes for a report server (with report writer), statistics/graphics server, and web server. These boxes would be set up and managed internally at HHN and communicate with the EDS data center only for pulling data from the transactional database as required.

The HHN/OLS v2.0 core reporting framework currently under discussion is highly consistent with the reporting requirements for HHN/LDC. As such, work on HHN/LDC and HHN/OLS v2.0 needs to be synchronized. In particular, requirements and design for the reporting component of HHN/OLS v2.0 need to be defined before any work on the reporting component of HHN/LDC is done. HHN Software Products has a Preliminary High-Level Requirements and Design document for HHN/OLS v2.0 Batch Reporting. That document is currently in circulation within HHN Engineering.

Since the reports will consist of text and graphs, there needs to be some way to combine these items and also produce the graphs without a user interface interaction. For this and other reasons, it is suggested that the reports be produced in PDF. PDF format is widespread and makes it easier to control layout than with HTML and other formats. With PDF, the report will be read-only and accessible from a variety of systems.

The following section describes a reporting architecture that provides significant scalability and workflow efficiencies. The architecture will allow subscribers to automate report generation and distribution. The following sections are consistent with the Preliminary High-Level Requirements and Design document for HHN/OLS v2.0 Batch Reporting, and the reader is referred to that document for additional detail.

5.5.1 Reporting Architecture

The proposed reporting architecture is based around a thin client web-browser user interface. The user interface displays a list of reports and enables reports to be scheduled or interactively run. Report results are automatically archived and managed in a hive, are available for viewing via role-based security, and can be automatically sent to other people as appropriate.

The server-side architecture is asynchronous whereby a user connects, requests a report, and can either wait for the report or disconnect and get the report later. The asynchronous design provides more scalability since reports can be queued and

processed by the report server. The asynchronous architecture also handles problems that could occur with someone on a bad connection; if the connection gets dropped, the report will be waiting when they get reconnected. The report server allows for the scheduling of reports, if those reports are run on a consistent basis.

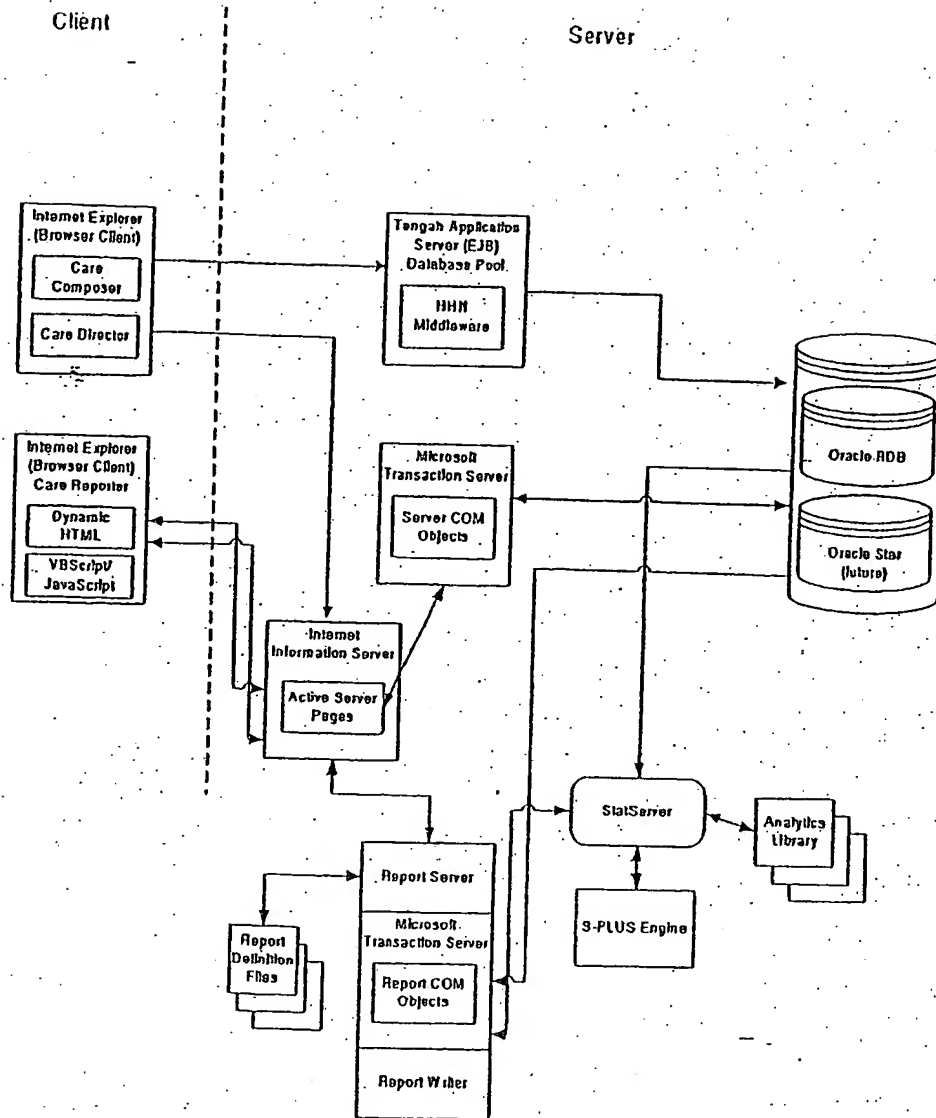
The central points of action in the architecture are the middleware components, which act as traffic cops handling interactions between the other components. The middleware components use the report writer to create reports that are sent back to a web page. The middleware handles getting data and analyses from the statistical/graphical engine and publishing the data or sending the output to the report writer.

The report writer allows for creation of report templates that can be easily modified at runtime to handle the ad-hoc nature of report options. The report writer handles the creation of the reports and the export of reports in various file formats. On the server-side, the report server uses the middleware and the report writer to process reports that are returned to the web server. When running reports on the server, the web server handles all user interaction with the server.

A report server is needed to manage the security, scheduling, and distribution of reports. There are available products that suit the needs of HHN applications without HHN having to build a report server. Currently, Report2Web has been reviewed. Others currently being reviewed are Brio.Report, Actuate, and WebFocus. The main purpose of the report server is to manage reports so that users can request reports, retrieve them later, and rerun reports using saved settings. On the web server, a user's security level determines the reports a user can run. The report server allows a user access to only the reports that the user ran or ones in "public" folders. The report server processes reports requested by users via the web server. The parameters and other report information are read from the web server and used to create the desired report with the correct options. The report server interacts with the middleware components to create reports using the report writer components and output from the statistical/graphical engine.

The statistics/graphics server manages sessions in which specific graphical analyses are run depending on the required reports and personal data. Currently, StatServer from MathSoft has been evaluated. This readily handles the data analysis sections of reports, creating graphs or data sets for display in reports. The database system is currently an Oracle database at EDS.

When the user selects a report, chooses options, and submits the report, the middleware handles the interaction with the statistics/graphics server. For example, an instance of the statistics/graphics engine is created via its Open method, and a new analysis object is created. Then, arguments and data associated with the analysis are passed to the analysis. After this, the Run method for this analysis object is called. The results are returned to a file, which contains the information relevant to the report. The image and/or summary statistics is then embedded into the report by the middleware.



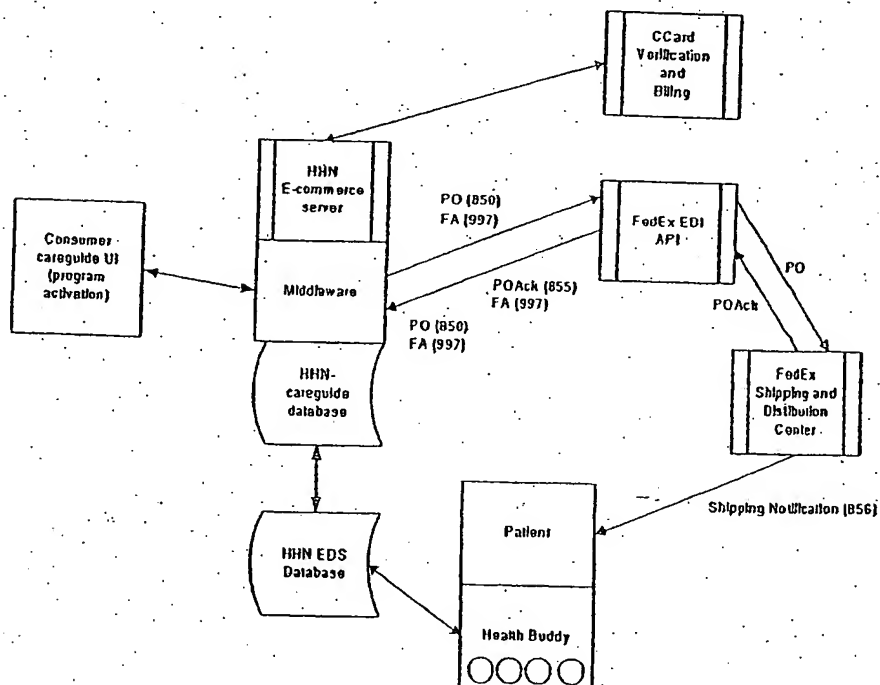
5.6 E-Commerce and Fulfillment

Additional server-side processing will be required to validate the credit card for the billing processes. The server will need to connect to a credit validation service to be able to process the order on-line. This will require extra middleware and/or an E-Commerce server to handle all of this processing.

A summary of E-commerce servers is provided as an appendix. For the HHN/LDC application, at first blush, we think the IBM Net.Commerce product would work well. This would need to be investigated further in association with current and anticipated future commerce requirements.

Fulfillment will involve interaction with the FedEx system currently in development. As we understand it, an API to the FedEx EDI factory will be available and we will be able to programmatically configure transactions and exchange transaction components.

The FedEx EDI interaction may look like the following:



The HHN/LDC application development will need to stay close to developments in the FedEx fulfillment system and to integrate accordingly.

5.7 Overall Design Issues

It is envisaged that HHN/LDC would address the requirements described above through a new thin client web user interface that facilitates communication with the Health Buddy via the HHN/OLS. The selected content topics would be linked to dialogues in the Data Center. These would then be run remotely over the Health Buddy appliance. This thin client user interface would also communicate with a report server, graphics server, and web server that would pull data from the HHN/OLS Data Center, run reports, and link reports to the family member's web page.

Many of the architectural issues discussed herein are currently being discussed by the HHN Architecture team. Some of these issues, while specific to the LDC project, apply more generally to a more flexible next generation HHN/OLS system. In particular, the architecture described above would provide a flexible, asynchronous, server-side reporting system for the core system. The scalability and the asynchronous nature of the proposed reporting architecture will provide a fast user experience while managing demands on server resources. The major areas that need improvement for this project are more dynamic scheduling of content and reporting/alerting of users.

6 Going Forward

6.1 Key Business Analysis Considerations

Careguide.com

The case for developing this product lies in the potential business relationship with Careguide.com. Specifically, given that this is a serious opportunity, an HHN team needs to meet with Careguide.com in order to gain an understanding of:

- Careguide.com's current product and product development milestones
- Key goals and requirements of this application from Careguide.com's perspective
- How and where the project will provide profits to HHN and to Careguide.com
- Risks for Careguide.com and HHN
- Who will own and develop ancillary business opportunities

6.2 Software Lifecycle Development

HHN Software Products has the following phased software lifecycle development process:

1. High level requirements and design
2. Detailed design
3. Development stage 1
4. Deployment as beta
5. Development stage 2
6. Commercial deployment

Typically phase 1 takes one to two months, depending on availability of solid requirements and phase 2 takes approximately two months. Milestones and schedules for stages beyond this can not be determined until the detailed design is in place.

The development of the HHN/LDC system will have to closely follow the other changes being made in the core HHN system. Many of the major changes required to make the HHN/LDC successful are in discussion as changes to the core system. The HHN/LDC requirements will be helpful in defining changes that need to be made in the core system, changes that will assist in the development of the HHN/LDC service going forward.

6.3 Next Steps

Discussions with careguide.com need to be contained to developing an understanding of the potential relationship, their current product and product development milestones, and key goals and requirements of this application from careguide.com's perspective.

Conditional on the business case and interest, the following internal resources and activities are required:

1. **HHN Software Products Involvement.** HHN Software Products to meet with careguide.com in order to begin a software business analysis and software requirements/design process. Some issues involved in this process are addressed above. This work would result in a Detailed Design document for the software build.
2. **HHN Marketing Involvement.** HHN Marketing to develop a concept document and a marketing requirements document for this project.
3. **HHN Clinical Involvement.** HHN Clinical Department to contribute to the concept document, the MRD, and the Detailed Design document.
4. **HHN Engineering Involvement.** HHN Engineering to be involved in any changes to the current middleware and Care applet functionality as described above.
5. **HHN QA Involvement.** HHN QA to be involved in testing and deploying any system built, and estimates of their time would need to be included in any project plan.
6. **HHN Supply Chain Involvement.** HHN Supply Chain to be involved in setting up the eCommerce server and the fulfillment and billing processes.

Appendix: E-Commerce Servers

E-Commerce servers come in four broad classes:

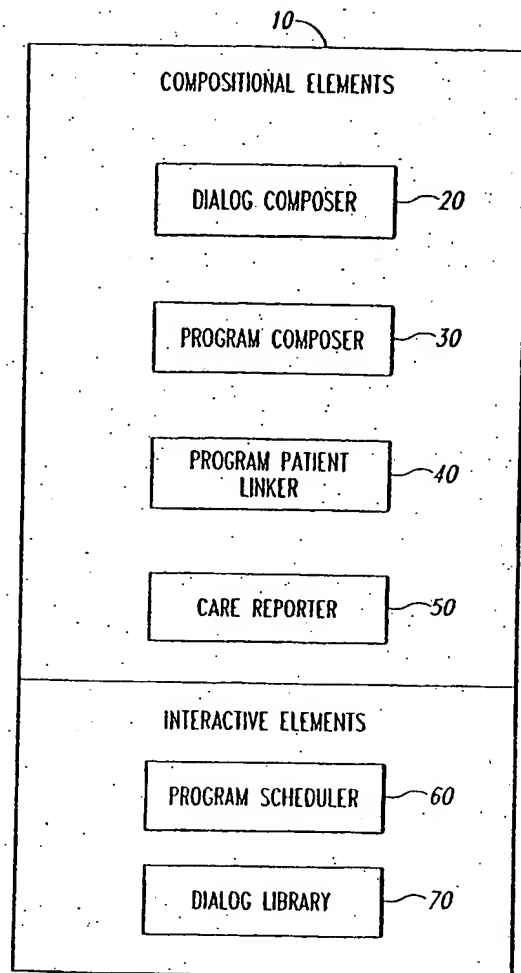
Web Storefronts are shrink-wrapped catalog products that enable simple order entry via a web browser. They typically provide store creation wizards, sample storefronts, and a payment system. Additional functions include catalog builders, search engines, shopping carts, and order tracking. No gateways or APIs to legacy, back-fulfillment, customer support, or inventory systems are usually provided. Links are limited to EDI, messaging, screen-scraping, and flat data. Web storefronts typically run on NT and some UNIX platforms and are priced in the range \$1000 to \$20,000. Vendors include IBM Net.Commerce (www-4.ibm.com/software/commerce/netcommerce), Open Market (www.openmarket.com/products), SpaceWorks (www.spaceworks.com).

Integrated Web Catalogs are shrink-wrapped customizable storefronts with shopping carts, customer-specific pricing abilities, customer account management functions, and product sales reporting. Additional functionality includes message based or screen scraping links to inventory and accounting systems. Integrated web catalogs typically run on NT and UNIX platforms and are priced in the range \$10,000 to \$50,000. Vendors include CommerceOne (www.commerceone.com), Clarus (www.claruscorp.com), and Ariba (www.ariba.com/corp/AribaSolutions/overview.asp).

Web Server Tool Sets are components and programming tools that enable users and integrators to build EC functional servers with gateways or APIs to back-office applications. Features include shopping carts, customer-specific product configuration, customer-specific pricing abilities, and customer account management functions. Web server tool sets typically run on NT and UNIX platforms and are priced in the range \$5,000 to \$250,000. Vendors include Harbinger (www.harbinger.com), Microsoft Site Server, Oracle, and Procurenet (www.procurenet.com).

Enterprise Web Servers are non shrink-wrapped, customized solutions incorporating storefront, integrated catalog, and server tools with robust, object-oriented APIs and gateways into multiple legacy EC systems. Enterprise web servers typically run on NT and UNIX platforms and are priced in the range \$50,000 to \$500,000. Vendors include Connect (www.connectinc.com/) and Broadvision (www.broadvision.com).

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*Fig. 1*

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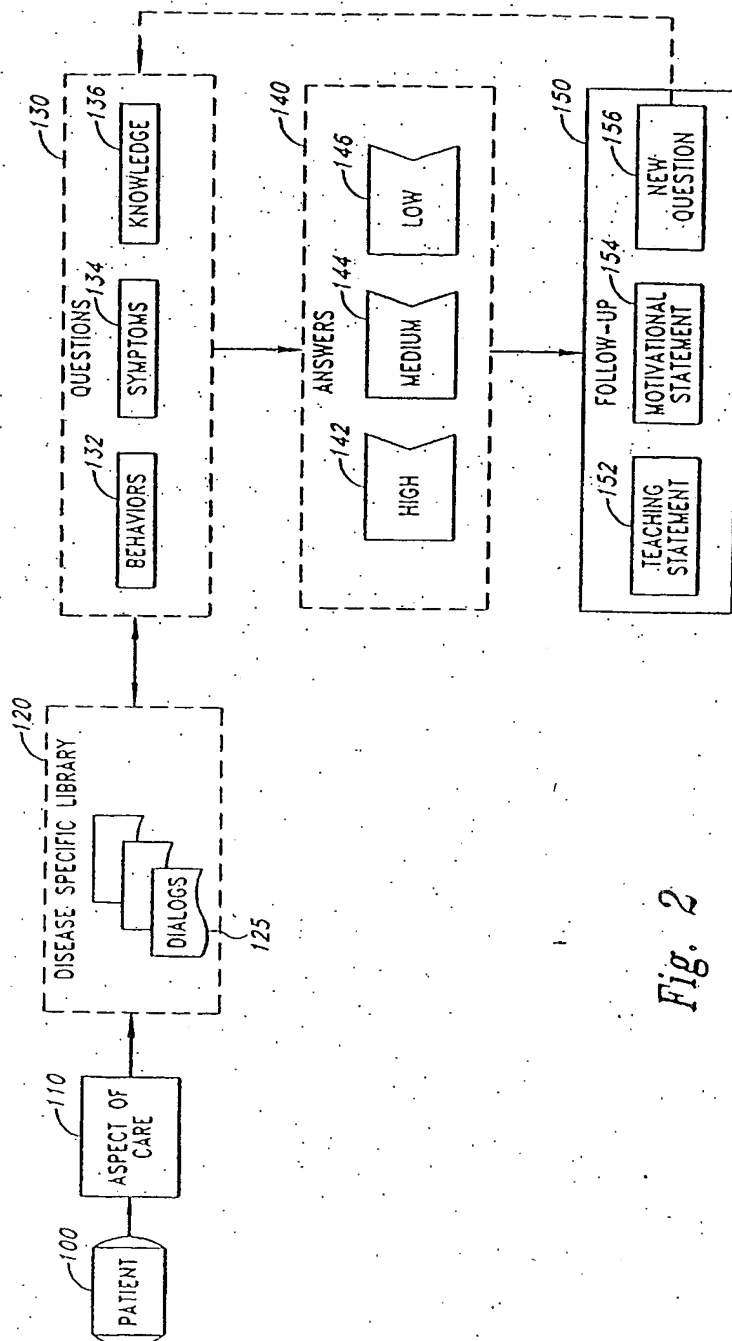
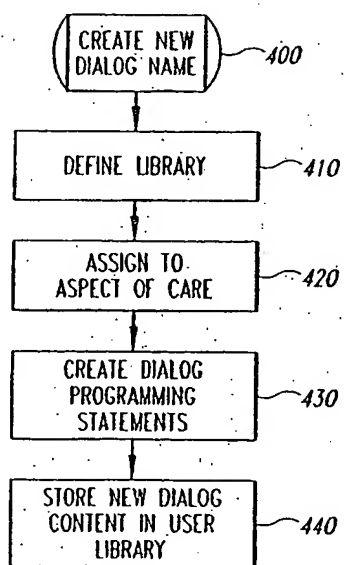
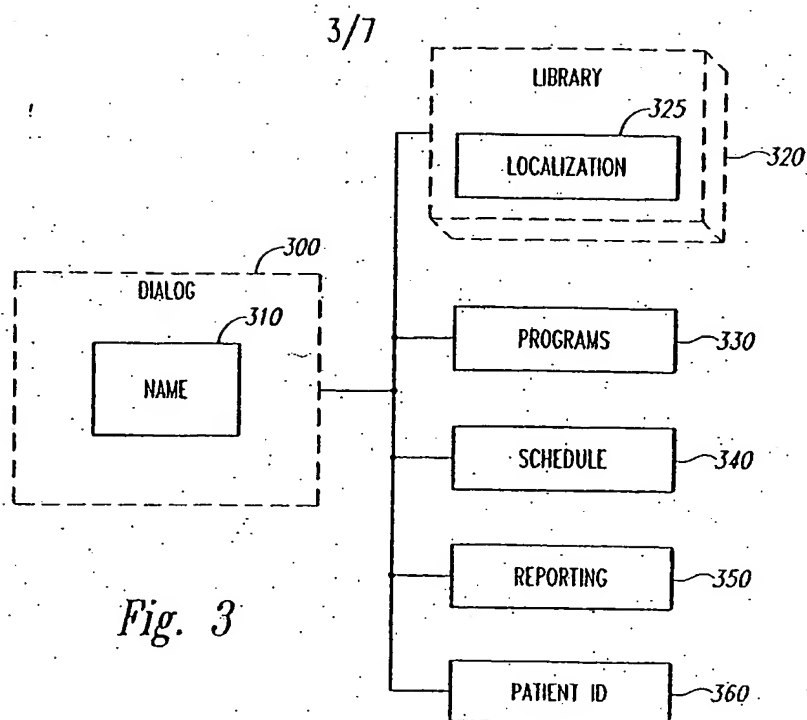


Fig. 2



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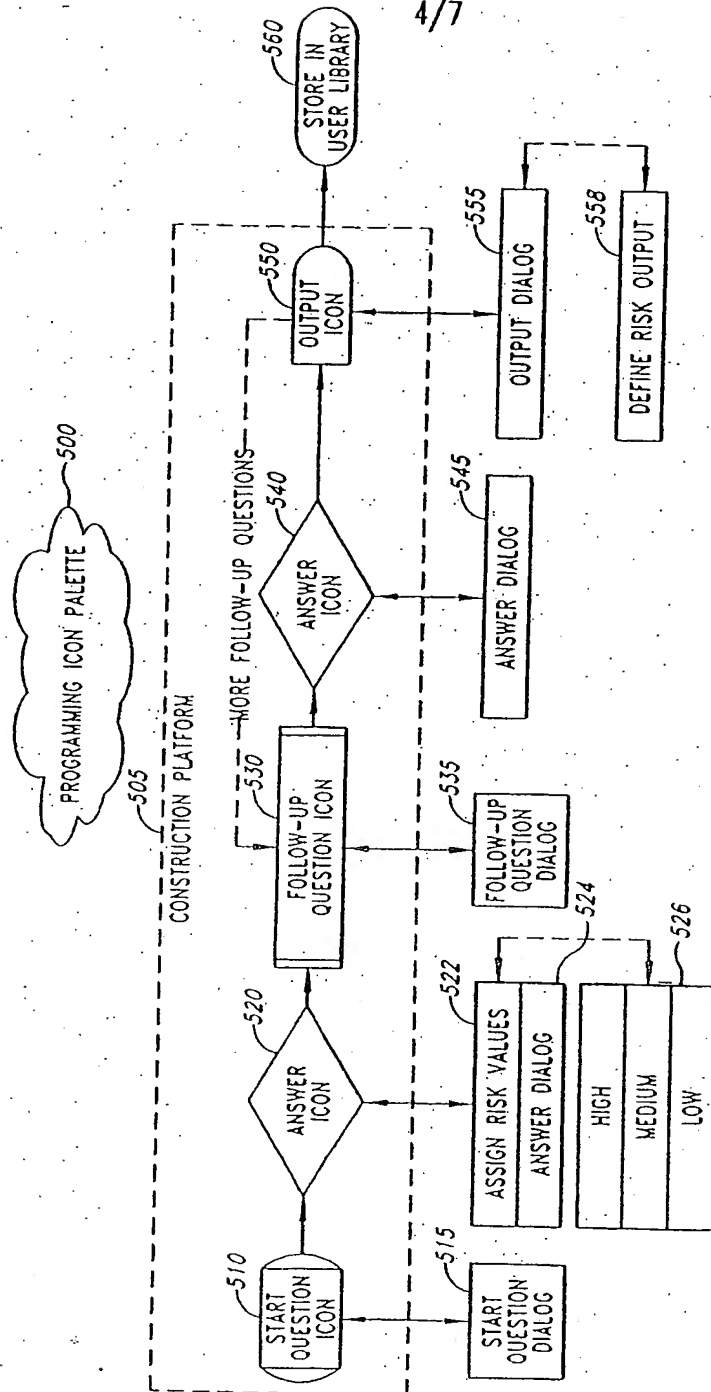


Fig. 5

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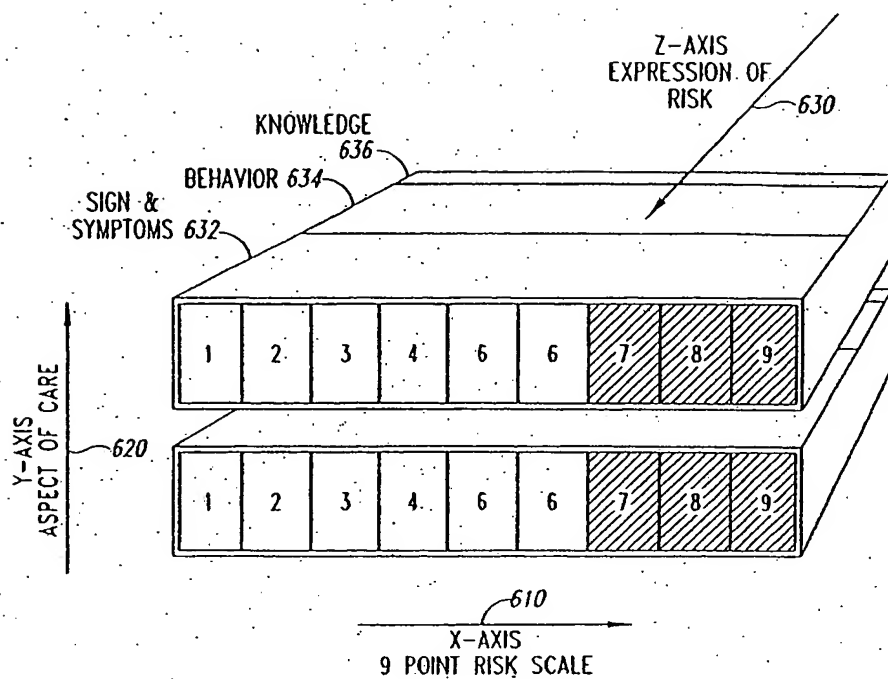


Fig. 6

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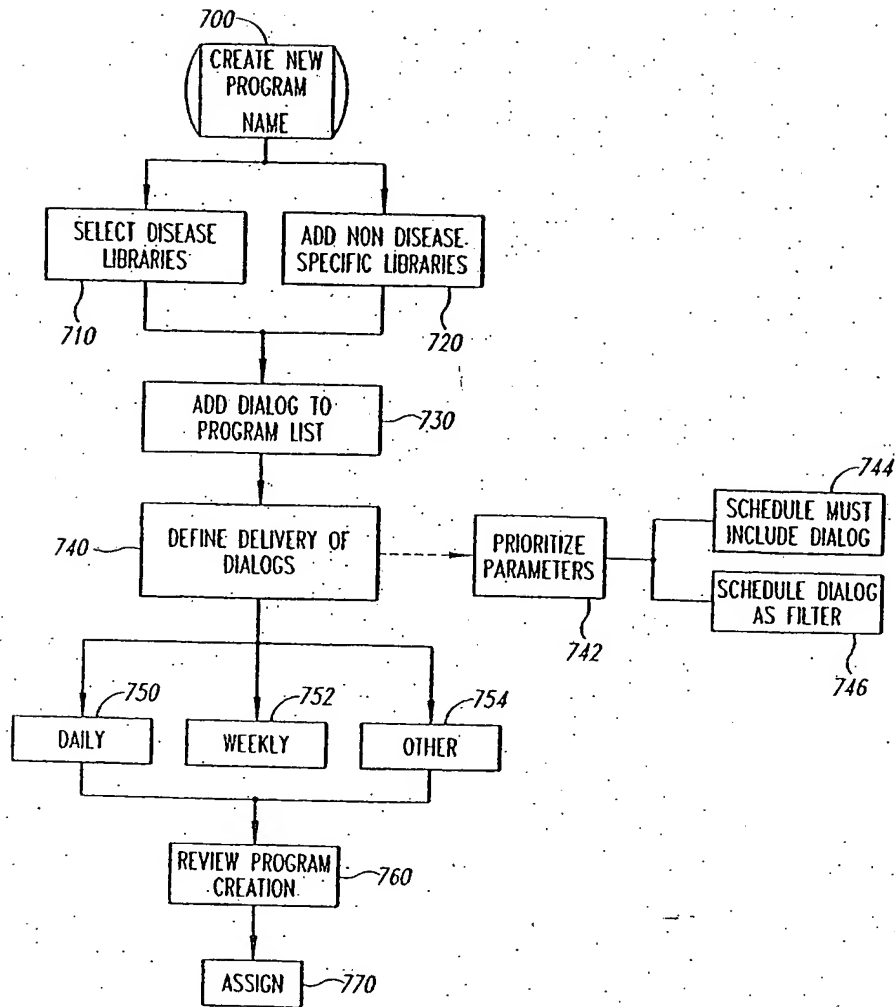


Fig. 7

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Fig. 8

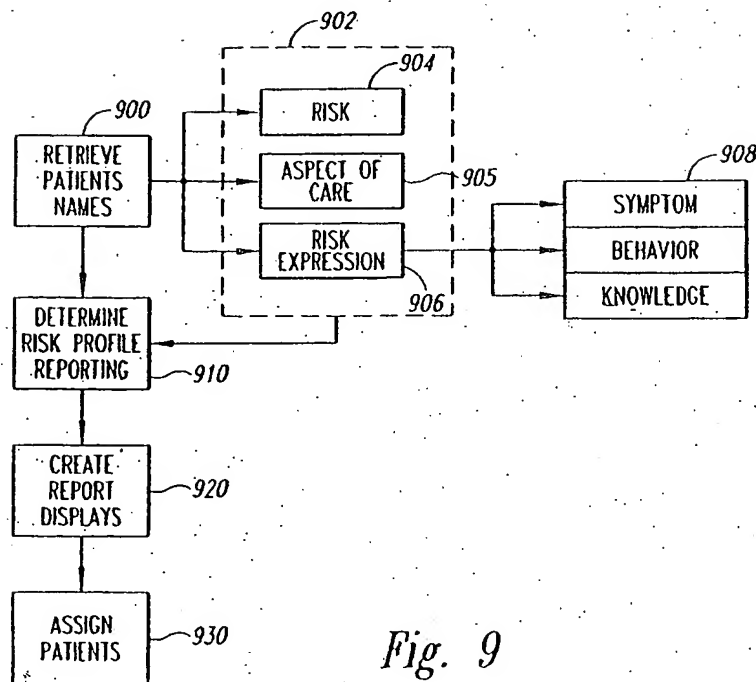
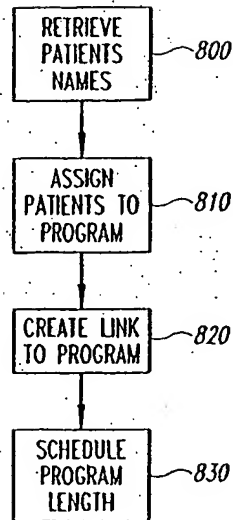


Fig. 9

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US01/08614

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : G06F 17/60

US CL : 705/3

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 705/3

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WEST, DIALOG

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,897,493 A (BROWN) 27 April 1999, (27.04.1999), column 4, lines 45-65, column 5, lines 9-62, column 6, lines 25-29, column 7, lines 63-67, column 8, lines 1-30.	1-5, 6-7, 9-13, 15-16, 18-19
Y		6, 8, 14, 17
Y	US 5,517,405 A (MCANDREW ET AL.) 14 May 1996 (14.05.1996), column 3, lines 55-59, column 6, lines 65-67, column 7, lines 1-4.	6, 8, 14, 17
A	US 5,978,603 A (BROWN) 06 July 1999 (06.07.1999), abstract.	1-19
A	US 5,574,828 A (HAYWARD ET AL.) 12 November 1996 (12.11.1996), abstract.	1-19

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

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document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

Z

document member of the same patent family

Date of the actual completion of the international search

23 May 2001 (23.05.2001)

Date of mailing of the international search report

21 JUN 2001

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